

Exhibit 6

Page 1

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3

4 IN RE: JOHNSON & JOHNSON MDL NO:
5 TALCUM POWDER PRODUCTS 16-2738 (MAS)(RLS)
6 MARKETING, SALES PRACTICES,
7 AND PRODUCTS LIABILITY
8 LITIGATION
9

10
11 Monday, July 8, 2024
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13

14 Remote Deposition of JOHN KORNAK, PhD,
15 conducted at the location of the witness in Vienna,
16 Austria, commencing at 10:04 a.m., by and before
17 Robin L. Clark, Registered Professional Reporter and
18 Notary Public in and for the Commonwealth of
19 Pennsylvania and the State of New Jersey.
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22
23
24

Page 2	Page 4
<p>1 REMOTE APPEARANCES:</p> <p>2</p> <p>3 LEVIN, PAPANTONIO, RAFFERTY LAW FIRM</p> <p>4 BY: CHRISTOPHER V. TISI, ESQ.</p> <p>5 316 South Baylen Street, Suite 600</p> <p>6 Pensacola, Florida 32502-5996</p> <p>7 850-435-7176</p> <p>8 ctisi@levinlaw.com</p> <p>9 For the Plaintiffs</p> <p>10</p> <p>11 BEASLEY ALLEN LAW FIRM</p> <p>12 BY: MARGARET M. THOMPSON, ESQ.</p> <p>13 218 Commerce Street</p> <p>14 Montgomery, Alabama 36104</p> <p>15 800-898-2034</p> <p>16 margaret.thompson@beasleyallen.com</p> <p>17 For the Plaintiffs</p> <p>18</p> <p>19 ASHCRAFT & GEREL, LLP</p> <p>20 BY: MICHELLE A. PARFITT, ESQ.</p> <p>21 1825 K Street, N.W., Suite 700</p> <p>22 Washington, D.C. 20006</p> <p>23 202-759-7648</p> <p>24 mparfitt@ashcraftlaw.com</p> <p>For the Plaintiff Steering</p> <p>Committee and the MDL</p> <p>KING & SPALDING, LLP</p> <p>BY: KATHRYN S. LEHMAN, ESQ.</p> <p>1180 Peachtree Street, N.E.</p> <p>Atlanta, Georgia 30309</p> <p>404-572-2716</p> <p>klehman@kslaw.com</p> <p>For the Defendants</p>	<p>1 I N D E X</p> <p>2 WITNESS PAGE</p> <p>3 JOHN KORNAK, PhD</p> <p>4 BY MR. TISI: 7</p> <p>5 BY MS. LEHMAN: 407</p> <p>6</p> <p>7 E X H I B I T S</p> <p>8 NUMBER DESCRIPTION MARKED</p> <p>9 Kornak</p> <p>10 Exhibit 1 Expert Report 10</p> <p>11 Exhibit 2 Curriculum Vitae 29</p> <p>12 Exhibit 3 Billing Statement 19</p> <p>13 Exhibit 4 Environmental Factor 173</p> <p>Article from NIH</p> <p>14 Exhibit 5 ASCO Publication 182</p> <p>15 Exhibit 6 Harris 2024 Article 191</p> <p>16 Exhibit 7 Terry Paper 2013 193</p> <p>17 Exhibit 8 O'Brien (2024) Paper 10</p> <p>18 Exhibit 9 Katie O'Brien, PhD, Bio 129</p> <p>19 Exhibit 10 Dale Sander, PhD, Bio 125</p> <p>20 Exhibit 11 Nicolas Wentzensen, MD, 133</p> <p>21 PhD, Bio</p> <p>22 Exhibit 12 Clarice Weinberg, PhD, bio 130</p> <p>23 Exhibit 13 OC3 Cohort Profile 136</p> <p>24 Exhibit 14 IARC Monographs on the 149</p> <p>Identification of</p> <p>Carcinogenic Hazards to</p> <p>Humans</p>
Page 3	Page 5
<p>1 REMOTE APPEARANCES, continued:</p> <p>2</p> <p>3 LAW OFFICES OF REILLY, McDEVITT</p> <p>4 & HENRICH, P.C.</p> <p>5 BY: BRANDY HARRIS, ESQ.</p> <p>6 3 Executive Campus, Suite 310</p> <p>7 Cherry Hill, New Jersey 08002</p> <p>8 856-317-7188</p> <p>9 bharris@rmh-law.com</p> <p>10 For the Personal Care Products</p> <p>11 Council</p> <p>12</p> <p>13 ALSO PRESENT:</p> <p>14</p> <p>15 JEFFERY WRIGHT</p> <p>16</p> <p>17 -----</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1</p> <p>2 Exhibit 16 O'Brien (2023) 114</p> <p>3 Exhibit 17 Sister Study Questionnaire 215</p> <p>4 Exhibit 18 Gonzalez Study 112</p> <p>5 Exhibit 20 Royston and White Paper 315</p> <p>6 Exhibit 21 JAMA Article 299</p> <p>7 Exhibit 22 Chang Study 115</p> <p>8 Exhibit 23 Trabert Article 414</p> <p>9 Exhibit 24 Publication History 165</p> <p>10 Exhibit 25 O'Brien (2020) Study 113</p> <p>11 Exhibit 26 O'Brien Response to Letter 117</p> <p>12 to the Editor</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

<p style="text-align: right;">Page 6</p> <p>1 DEPOSITION SUPPORT INDEX</p> <p>2</p> <p>3 -----</p> <p>4 Direction to Witness Not to Answer</p> <p>5 Page Line</p> <p>6 406 14</p> <p>7 Request for Production of Documents</p> <p>8 Page Line</p> <p>9 NONE</p> <p>10 Question Marked</p> <p>11 Page Line</p> <p>12 NONE</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 8</p> <p>1 Austria, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. I have sent you a box of</p> <p>4 documents, most of which we will use, but</p> <p>5 I'm not sure of all of them. Do you have</p> <p>6 that in front of you, sir?</p> <p>7 A. I do.</p> <p>8 Q. Have you opened the box?</p> <p>9 A. I've opened the box.</p> <p>10 Q. Okay. And do you have</p> <p>11 everything in front of you so that we can</p> <p>12 go through things in --</p> <p>13 A. I haven't removed the tape as</p> <p>14 of yet though.</p> <p>15 Q. Okay. Why don't you go ahead</p> <p>16 and do that and we can get started?</p> <p>17 A. Okay.</p> <p>18 -----</p> <p>19 (Discussion was held off the record.)</p> <p>20 -----</p> <p>21 BY MR. TISI:</p> <p>22 Q. Tell me when you're ready,</p> <p>23 sir.</p> <p>24 A. Okay. Ready.</p>
<p style="text-align: right;">Page 7</p> <p>1 THE STENOGRAPHER: All parties</p> <p>2 to this deposition are appearing</p> <p>3 remotely and have agreed to the</p> <p>4 witness being sworn in remotely.</p> <p>5 Due to the nature of the remote</p> <p>6 reporting, please pause briefly</p> <p>7 before speaking to ensure all</p> <p>8 parties are heard completely.</p> <p>9 Counsel will be noted on the</p> <p>10 stenographic record.</p> <p>11 -----</p> <p>12 JOHN KORNAK, PhD, having</p> <p>13 been duly sworn, was examined and</p> <p>14 testified as follows:</p> <p>15 -----</p> <p>16 BY MR. TISI:</p> <p>17 Q. Would you please state your</p> <p>18 name for the record, please?</p> <p>19 A. Yeah, John Kornak.</p> <p>20 Q. Dr. Kornak, are you a</p> <p>21 biostatistician?</p> <p>22 A. I am.</p> <p>23 Q. Okay. We have placed before</p> <p>24 you or sent you -- you're actually in</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. Have you been hired by the</p> <p>2 lawyers defending Johnson & Johnson and LLT</p> <p>3 to offer opinions relating to a May 24</p> <p>4 study by NIH scientists called "Intimate</p> <p>5 Care Products and Incidence of</p> <p>6 Hormone-Related Cancers: A Quantitative</p> <p>7 Bias Analysis"?</p> <p>8 A. Yes, I was retained to give</p> <p>9 an independent opinion of that -- of that</p> <p>10 paper.</p> <p>11 Q. Okay. If I call it O'Brien</p> <p>12 (2024) to make it easier, would that be</p> <p>13 okay?</p> <p>14 A. That's fine, yes.</p> <p>15 Q. All right. Do you have a</p> <p>16 hard copy in front of you, sir?</p> <p>17 A. Yes, I have my --</p> <p>18 Q. You have your copy and just</p> <p>19 for the record, it's Exhibit No. 8 in the</p> <p>20 box --</p> <p>21 A. Okay.</p> <p>22 Q. -- in the binder. Yours</p> <p>23 doesn't have any -- yours does not have any</p> <p>24 markings on it, correct?</p>

<p style="text-align: right;">Page 10</p> <p>1 A. That's correct, there's no 2 markings. 3 ----- 4 (O'Brien (2024) Paper marked 5 Kornak Exhibit 8 for 6 identification.) 7 ----- 8 BY MR. TISI: 9 Q. Just to make it easier so you 10 don't have to go back and forth between the 11 binder, your report is going to be Exhibit 12 No. 1, which I understand you brought with 13 you and the O'Brien (2024) is Exhibit 14 No. 8. Do you see that in your binder? 15 A. Let me check. Yes, Exhibit 16 No. 1 looks like my report. And Exhibit 8 17 looks like the paper. 18 ----- 19 (Expert Report marked Kornak 20 Exhibit 1 for identification.) 21 ----- 22 BY MR. TISI: 23 Q. Okay. All right. And I 24 understand, just for the record, that you</p>	<p style="text-align: right;">Page 12</p> <p>1 I don't know that I would categorize it as 2 large, but the overall sample size was 3 large, but the number of cases was not as 4 large. 5 Q. Okay. But the study itself 6 is a 50,000 person study sponsored by the 7 NIH, correct? 8 A. And I'm only pausing because 9 I'm not sure whether NIH was the sponsor. 10 I have no reason to doubt that it was, 11 but -- 12 Q. Now, using -- I'm sorry, and 13 because we're on a Zoom, if I cut you off, 14 I don't do that intentionally and if you 15 cut me off, I will also agree that you're 16 not doing it intentionally and we'll try to 17 work with each other. 18 A. That sounds good. I just 19 wanted to check if you wanted me to search 20 through to make sure that -- I assume they 21 have it somewhere in a footnote. 22 Q. They do, and we'll get to 23 that. So let's just see if we can move 24 forward.</p>
<p style="text-align: right;">Page 11</p> <p>1 brought your report and O'Brien (2024) with 2 you, but they don't have any markings on 3 them, correct? 4 A. That's correct, no markings. 5 Q. And you didn't bring any 6 notes of any kind, correct? 7 A. No, no notes. 8 Q. Do you have any notes of any 9 kind related to your review of this study 10 or generating this report? 11 A. No, I don't have any notes. 12 Q. Okay. All right. Now, the 13 O'Brien (2024), which is Exhibit No. 8, 14 appeared in the peer review Journal of 15 Clinical Oncology, correct? 16 A. Yes. 17 Q. And it appeared less than two 18 months ago on May 15, 2024? 19 A. It was published on May 15, 20 2024, yes. 21 Q. And O'Brien (2024) paper you 22 stated for a large NIH cohort study called 23 the Sister Study, correct? 24 A. They used the Sister Study.</p>	<p style="text-align: right;">Page 13</p> <p>1 Now, using statistical 2 methods that we'll be discussing in this 3 deposition, including a quantitative bias 4 analysis, multiple imputation, and other 5 recall bias scenarios, this peer-reviewed 6 study concluded that genital talc use was 7 associated with ovarian cancer, 8 particularly in women who used it 9 frequently and for longer durations, 10 correct? 11 A. I don't fully agree with that 12 statement on a couple of levels. I would 13 hesitate to call recall -- what they did 14 for recall bias a statistical method. 15 Q. Okay. 16 A. And similarly for the 17 qualitative bias analysis too. And so can 18 you -- you mean what they said or what -- 19 Q. Yes, I'm stating what they 20 said. That's what they concluded. I 21 understand you have differences with their 22 conclusion, but their conclusion was, and 23 we can go to the paper itself, Exhibit 8, 24 page 2 in the box, it says "Knowledge</p>

<p style="text-align: right;">Page 14</p> <p>1 Generated, Genital talc use was positively 2 associated with ovarian cancer for a range 3 of plausible bias-correction scenarios, 4 with higher rates seen for frequent and 5 long-term users." 6 That's what the study said, 7 correct? 8 A. Well, that's what they -- the 9 authors say in these particular couple of 10 sentences, but they had also use words such 11 as support a positive association in the 12 conclusion in the abstract. And the 13 relevance talks about a measure confounding 14 could still be present. So that kind of 15 qualifies the statement a little bit, I 16 think. 17 Q. And they also concluded that 18 the association existed even after 19 adjusting for recall bias using various 20 scenarios that they discussed in the paper, 21 correct? 22 A. I don't know if that's the 23 precise wording. I remember something that 24 they said like that, but I don't agree with</p>	<p style="text-align: right;">Page 16</p> <p>1 BY MR. TISI: 2 Q. Correct. Okay. Now, from 3 what I can tell, you met with J&J's lawyers 4 to discuss preparing a litigation report 5 addressing the O'Brien (2024) study on 6 about May 20, 2024, five days after the 7 study was published, correct? 8 A. I don't recall meeting with 9 J&J lawyers on that date. I may have. 10 That's around the date that I was first 11 contacted about the case. 12 Q. And the goal was to generate 13 and submit the litigation report that 14 ultimately became Exhibit No. 1, correct? 15 A. That's not what I understood 16 the goal to be. I understood it to be that 17 I was to provide an independent review of 18 the O'Brien (2024) paper from my 19 biostatistical perspective. 20 Q. It's not entirely 21 independent, right? You were actually paid 22 \$50,000 to generate that report, correct? 23 MS. LEHMAN: Object to form. 24 THE WITNESS: It's correct</p>
<p style="text-align: right;">Page 15</p> <p>1 that. 2 Q. Okay. I understand you don't 3 agree with it. We're just trying to get 4 what the paper said and then we'll talk 5 about your criticisms, okay? 6 A. Okay. Do you want to -- 7 whereabouts -- do you want to read a 8 precise statement that they said or -- 9 Q. Actually, we'll get to that. 10 I'm not going to -- I'm not going to -- if 11 you don't understand that to be the 12 conclusion of the authors, then I will move 13 on. But do you understand that the 14 authors' general proposition was there was 15 a positive association even considering 16 recall bias and used various scenarios to 17 test that? 18 MS. LEHMAN: Object to form. 19 Asked and answered. 20 THE WITNESS: I would sort of 21 qualify that they would say they 22 had some evidence to support that 23 as being what they are saying. 24</p>	<p style="text-align: right;">Page 17</p> <p>1 that I was paid \$50,000 to generate 2 that report, but I approached it 3 from an independent perspective. 4 BY MR. TISI: 5 Q. Well, I wasn't in the room to 6 talk to you about my perspective, was I? 7 A. You are correct that you were 8 not in the room to talk about your 9 perspective, but I was not -- I reviewed 10 the paper itself. I took the paper, I 11 looked at it, I read it. It's my 12 perspective. 13 Q. Okay. We'll talk about that 14 in a moment, if we could. But it's fair to 15 say that you learned of this study through 16 litigation and not in the normal course of 17 your academic endeavors? 18 A. Yes, that's fair to say. 19 Q. Okay. And to be clear, 20 neither J&J or any of its subsidiaries in 21 the normal course of business contacted you 22 to help them understand this study, it was 23 the lawyers, true? 24 A. It was -- it was the lawyers</p>

<p style="text-align: right;">Page 18</p> <p>1 through Cornerstone Research. 2 Q. We'll talk about Cornerstone, 3 but the company itself, just to be clear, 4 the company never called you independently 5 and said, you know, we need to understand 6 this study, its strengths and its 7 weaknesses in our normal course of 8 business, did they? 9 MS. LEHMAN: Object to the 10 form. 11 THE WITNESS: J&J didn't 12 contact me. 13 BY MR. TISI: 14 Q. It was the lawyer? 15 MS. LEHMAN: Object to form. 16 BY MR. TISI: 17 Q. Through Cornerstone, it was 18 the lawyers? 19 A. Cornerstone Research 20 contacted me. 21 Q. Right, but they were 22 operating at the direction of the lawyers, 23 true? 24 A. I don't know what their exact</p>	<p style="text-align: right;">Page 20</p> <p>1 identification.) 2 ----- 3 BY MR. TISI: 4 Q. Okay. On May 20, 2024, you 5 reviewed the O'Brien (2024) quantitative 6 bias paper and meeting with Cornerstone and 7 legal team. 8 Do you see that? 9 A. Yes. 10 Q. Does that refresh your 11 recollection the first day you ever spoke 12 to anyone about this paper, you spoke with 13 Cornerstone and the lawyers for J&J? 14 A. Okay. So I certainly accept 15 what I have here in the statement. None of 16 it refreshes my memory exactly, but I 17 remember I had a call with Cornerstone and 18 then a meeting was set up to also meet with 19 the legal team and that would have been 20 later in the day given that it was on the 21 same day. It was a separate -- 22 Q. All right. But my point is 23 that you said that you were going to do an 24 independent analysis of this paper, but at</p>
<p style="text-align: right;">Page 19</p> <p>1 relationship is with the lawyers and J&J 2 and I didn't ask. 3 Q. Okay. We're going to be 4 talking about Cornerstone in a moment, but 5 your initial meeting with them on your 6 billing statement states you met with J&J's 7 lawyers and Cornerstone on the first day 8 where you were retained to look at this 9 study. Does that refresh your 10 recollection? 11 A. I mean, if I -- I have no 12 reason to doubt it. I would like, you 13 know, to -- 14 Q. Well, let's -- 15 A. -- take a look. 16 Q. I'm a little bit out of 17 order, but let's take a look at it. If you 18 would look at your statement, Exhibit No. 3 19 in your binder, which is your billing 20 statement. 21 A. Yes. 22 ----- 23 (Billing Statement marked 24 Kornak Exhibit 3 for</p>	<p style="text-align: right;">Page 21</p> <p>1 the time that you first got this study, you 2 met with Cornerstone and J&J's lawyers and 3 nobody else, true? 4 MS. LEHMAN: Object to form. 5 THE WITNESS: Can you repeat 6 that question? It seemed a 7 little -- 8 BY MR. TISI: 9 Q. Yes. You got a copy of the 10 paper on or about May 20, 2024, correct? 11 A. I believe that to be true. 12 Q. And on the same day, you 13 spoke to J&J's lawyers, true? 14 A. Yes. 15 Q. And there was nobody else 16 there, nobody from, for example, my side of 17 the table that would talk to you about our 18 perspective on the 2024 paper, correct? 19 MS. LEHMAN: Objection. Asked 20 and answered. 21 THE WITNESS: There was 22 certainly no one -- you were not 23 there. 24</p>

<p style="text-align: right;">Page 22</p> <p>1 BY MR. TISI:</p> <p>2 Q. Right. And --</p> <p>3 A. I don't know to what extent</p> <p>4 I'm allowed to talk about what was in the</p> <p>5 meeting since it was -- it would be</p> <p>6 privileged, but really it was more about my</p> <p>7 CV.</p> <p>8 Q. Okay. Now, you also -- all</p> <p>9 right. We'll talk about that in a moment.</p> <p>10 Now, you understood that now</p> <p>11 and you understood at that time that the</p> <p>12 purpose of that meeting was get to you to</p> <p>13 write a litigation report in this</p> <p>14 litigation relating to the O'Brien (2024)</p> <p>15 study, correct?</p> <p>16 A. Yeah, I was asked to</p> <p>17 independently review the O'Brien (2024)</p> <p>18 paper.</p> <p>19 Q. And, in fact, you produced a</p> <p>20 report for J&J's lawyers supporting the</p> <p>21 position that the paper is flawed and</p> <p>22 unreliable on May 29, 2024, correct, less</p> <p>23 than ten days after meeting with the</p> <p>24 lawyers and Cornerstone, correct?</p>	<p style="text-align: right;">Page 24</p> <p>1 the paper.</p> <p>2 BY MR. TISI:</p> <p>3 Q. And you knew that that report</p> <p>4 would then be used in litigation, correct?</p> <p>5 A. I assumed it was for the</p> <p>6 case, yes.</p> <p>7 Q. And you in fact did generate</p> <p>8 a report and it was filed on May 28, eight</p> <p>9 days later, correct?</p> <p>10 A. Correct.</p> <p>11 Q. All right. And that report</p> <p>12 is marked in your binder as Exhibit 1,</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And if you go to</p> <p>16 page 2 to 4 of your report, page 2 to 4 of</p> <p>17 your report, you summarize and you say that</p> <p>18 even though the authors find a</p> <p>19 statistically significant association</p> <p>20 between genital talc use and ovarian</p> <p>21 cancer, even considering potential biases,</p> <p>22 O'Brien (2024) was flawed and unreliable,</p> <p>23 correct?</p> <p>24 A. Sorry, I'm just trying to</p>
<p style="text-align: right;">Page 23</p> <p>1 A. I would have to look at the</p> <p>2 date of my report. I don't -- I don't have</p> <p>3 any reason to doubt that was the date it</p> <p>4 was produced, but --</p> <p>5 Q. Well, if you take a look --</p> <p>6 if you take a look at your litigation</p> <p>7 report, Exhibit 1, on the front page, it</p> <p>8 says report of May 28, 2024; is that</p> <p>9 correct?</p> <p>10 A. Yes, but I would ask if you</p> <p>11 could repeat your question, because there</p> <p>12 was one part I didn't sort of agree with in</p> <p>13 particular.</p> <p>14 Q. Sure. You were retained and</p> <p>15 met with the lawyers from J&J on May 20,</p> <p>16 2024, with the goal of writing a litigation</p> <p>17 report, correct?</p> <p>18 MS. LEHMAN: Object to the</p> <p>19 form. Asked and answered.</p> <p>20 THE WITNESS: No, my goal was</p> <p>21 to review the O'Brien (2024) paper</p> <p>22 and then write a report on my</p> <p>23 review of that paper and that</p> <p>24 review was an independent review of</p>	<p style="text-align: right;">Page 25</p> <p>1 find the precise paragraph you're reading</p> <p>2 from on page 2 to 4?</p> <p>3 Q. On -- I'm sorry.</p> <p>4 A. Is it paragraph 10?</p> <p>5 Q. Yes. Correct.</p> <p>6 A. I'm sorry, what's the</p> <p>7 statement from paragraph 10?</p> <p>8 Q. "While the authors find a</p> <p>9 positive and consistently significant</p> <p>10 association between genital talc use (based</p> <p>11 on these adjustments)," which we will talk</p> <p>12 about, "and ovarian cancer, the authors'</p> <p>13 'imputations' of, 'corrections' to, and</p> <p>14 assumptions regarding genital talc use</p> <p>15 makes their analysis flawed and</p> <p>16 unreliable."</p> <p>17 A. I'm sorry, I thought you were</p> <p>18 saying paragraph 10. You're on</p> <p>19 paragraph 11 there, right?</p> <p>20 Q. Correct.</p> <p>21 A. Okay.</p> <p>22 Q. And that's what you -- that's</p> <p>23 your opinion, correct?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 26</p> <p>1 Q. And you reached that opinion 2 in eight days or less, correct? 3 A. Yes. 4 Q. Okay. Now, let's go to your 5 billing statement, Exhibit No. 3 and it 6 says you first reviewed O'Brien (2024) on 7 May 20, 2024. 8 Do you see that? 9 A. Well, yeah, I would agree 10 that's when I started reviewing it. 11 Q. Okay. All right. Well, you 12 reviewed it, did you read the whole thing 13 on May 20, 2024? 14 A. I mean, I don't know how you 15 would exactly define it. Did I read every 16 word in there, I don't think so. I think, 17 you know, the way I approach reading a 18 paper to review it is not to start on 19 page 1 and read through every word all the 20 way to the end. I often jump around and 21 then I often fill in the pieces. So I 22 can't say whether I read every piece of 23 that paper on the first day or not. 24 Q. Well, you did meet with the</p>	<p style="text-align: right;">Page 28</p> <p>1 question. Between the time that you first 2 met with Jessica Davidson on the 20th of 3 May and the time your report was filed on 4 the 28th or finalized on the 28th, how many 5 times did you meet with Ms. Davidson either 6 by phone or in person? 7 A. I don't recall that I even 8 met with her again since that initial 9 meeting until after my report was filed. 10 Q. Okay. And then after -- 11 A. I'm not saying that's for 12 certain, I just don't recall. 13 Q. Okay. 14 A. I don't know. 15 Q. Okay. And we'll talk about 16 after your report in a moment. 17 Now, we've talked several 18 times about Cornerstone. Could you tell me 19 what Cornerstone is? 20 A. I don't know exactly. 21 They're some kind of company that supports 22 legal cases and they were made available to 23 me in an administrative support role. 24 Q. Well, actually, in your</p>
<p style="text-align: right;">Page 27</p> <p>1 legal team on the first day, correct? 2 MS. LEHMAN: Objection. Asked 3 and answered. 4 THE WITNESS: I did meet with 5 the legal team on that day. 6 BY MR. TISI: 7 Q. Okay. Who did you -- who on 8 the legal team did you meet? 9 A. There was Jessica Davidson 10 and another lady that I don't recall the 11 name of, but I have not seen on matters 12 since, so. 13 Q. Okay. Have you met with 14 Jessica Davidson after this initial meeting 15 on May 20, 2024? 16 A. Yes, I have. 17 Q. How many times? 18 A. I would estimate somewhere 19 between five and ten times. 20 Q. Okay. Those are not 21 reflected on your billing statement? 22 A. Sorry, can I just -- between 23 which dates? I didn't -- I thought -- 24 Q. Well, that was going to be my</p>	<p style="text-align: right;">Page 29</p> <p>1 report -- in your CV, which I have had 2 marked as -- I'm a little out of order, but 3 in your CV, which I've had marked as 4 Exhibit No. 2, you actually list 5 Cornerstone as somebody with whom you work. 6 Am I correct about that? 7 A. Yes, I worked with them 8 previously. 9 - - - - - 10 (Curriculum Vitae marked 11 Kornak Exhibit 2 for 12 identification.) 13 - - - - - 14 BY MR. TISI: 15 Q. Okay. And are they a company 16 that finds experts for companies who are 17 looking for experts? 18 A. I don't know that that's what 19 the complete -- the company completely is. 20 Like I say, they also provided me with 21 administrative support. I don't know 22 completely what the company does. 23 Q. Well, you listed -- 24 A. Based on experts, they found</p>

<p style="text-align: right;">Page 30</p> <p>1 me, so I would go along with that, but as 2 far as I know, I haven't researched them to 3 know beyond that. 4 Q. So you work with a company 5 that you don't know what they do? 6 MS. LEHMAN: Object to form. 7 BY MR. TISI: 8 Q. You list them on your CV and 9 you and work with them -- 10 A. I don't work for Cornerstone. 11 I mean, they retain me -- they, through the 12 lawyers, through them retained me to work 13 on this case. I don't work for them. 14 Q. Well, it says on your -- and 15 you can look on your CV, which is Exhibit 16 No. 2 -- 17 A. Uh-huh. 18 Q. -- page 14 of 77, it has that 19 you've worked with Cornerstone Research 20 from 2022 to 2023, that would be through 21 2024, correct? 22 A. Well, the case that I was 23 working on with Cornerstone Research, 2022 24 to 2023, I'm no longer involved in. So,</p>	<p style="text-align: right;">Page 32</p> <p>1 reveal that information. 2 THE WITNESS: Yeah, I don't 3 believe this part of it is 4 privileged in the sense that 5 they -- that Cornerstone did 6 contact me about that particular 7 case. 8 BY MR. TISI: 9 Q. And it said that you were 10 identified as an expert witness, correct? 11 A. I would say a potential 12 expert witness, but -- 13 Q. Did you generate a report? 14 A. I'm kind of nervous now, 15 because I don't know if that's sort of 16 getting into what is privileged information 17 or not. 18 Q. Well, I'm just asking you, 19 did you generate a report? 20 MS. LEHMAN: So let me just 21 jump in here, John. If you were 22 disclosed as a witness, then you 23 can talk about it. If you were -- 24 if you were purely a consulting</p>
<p style="text-align: right;">Page 31</p> <p>1 you know, my CV, as you can tell, is very, 2 very long and I don't necessarily -- I am 3 not able to keep every single thing up to 4 date, but, yes, now, I would update it and 5 say I have also done work with Cornerstone 6 in 2024. 7 Q. And we'll go through this 8 and, but you've worked with -- I'm sorry, 9 is somebody saying something? I'm sorry. 10 You have worked with Cornerstone in another 11 case they found you as an expert for 12 another company beginning in 2022, correct? 13 MS. LEHMAN: And let me 14 just -- let me just -- I just want 15 to caution John, because this is 16 not my client, but to the extent he 17 was a consulting litigation expert 18 who was not disclosed, I would just 19 tell him to be cautious about not 20 revealing privileged information. 21 And John would know the answer to 22 that, not me. I'm just putting 23 that out there to the extent that 24 it is privileged, he should not</p>	<p style="text-align: right;">Page 33</p> <p>1 witness so that you were not 2 disclosed, then information about 3 what you did would be privileged. 4 THE WITNESS: Yes, so I was 5 not disclosed, so. 6 BY MR. TISI: 7 Q. Okay. We'll get back to that 8 in a moment, but in terms of Cornerstone, 9 okay, you have been working with a company 10 that finds experts for litigation for -- 11 since at least 2022, correct? 12 A. You say working with? 13 Q. Yes. 14 A. I don't know if working with 15 is right. Again, I can't talk about the 16 previous case, but in this case, they're 17 kind of made available to me to provide 18 administrative support. So I don't know by 19 "working with" what you would mean. 20 Q. How did J&J find you in this 21 case? 22 A. Cornerstone found me. 23 Q. Okay. Cornerstone found you. 24 You're basically an expert that puts your</p>

<p style="text-align: right;">Page 34</p> <p>1 name in with Cornerstone and if Cornerstone 2 has a client that's looking for litigation 3 support and your CV matches, they connect 4 you, right? 5 A. That's not totally correct. 6 I didn't put my name in with Cornerstone. 7 Q. How does Cornerstone know 8 you? 9 A. I don't know for sure, but 10 I'm a well-known professor of biostatistics 11 at a leading medical institution. I'm on 12 the university website as a professor and 13 you see my CV, so they can look me up and 14 they can contact me and then people have 15 many -- people have done that for various 16 fields. 17 Q. Well, and they've done it at 18 least twice, they found you in the previous 19 case and they found you in this case, 20 right? True? 21 A. I mean, they found me in the 22 first case and then whether they found me 23 or they had my name on record, that's 24 another question.</p>	<p style="text-align: right;">Page 36</p> <p>1 don't know what their mechanism is. I 2 don't know what their relationship is with 3 their clients. I'm not clear on that. 4 Q. Well, you've actually worked 5 with law firms going back many years, true? 6 A. Yes. 7 Q. Okay. So Cornerstone 8 Research is kind of an extension of what 9 you were doing all along, true? 10 MS. LEHMAN: Object to form. 11 THE WITNESS: I find that 12 question, like, completely 13 confusing. 14 BY MR. TISI: 15 Q. Okay. Well, let's talk about 16 it then. Okay. If we can go back to the 17 prior page on your CV, you were working as 18 a statistical consultant for law firms 19 since at least 2015, correct, page 13 of 20 77? 21 A. Yes. 22 Q. You worked with Goodman 23 Neuman and Hamilton LLP as an expert 24 witness/statistical consultant, correct?</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. Right. So you basically -- 2 they basically had an ability to, you were 3 on record with Cornerstone, they connected 4 with the first defendant, which you worked 5 with as a consultant, and you also were 6 recalled by them to work with Johnson & 7 Johnson and their lawyers in this case, 8 true? 9 MS. LEHMAN: Object to form. 10 Asked and answered. 11 THE WITNESS: Recalled, I 12 would consider recalling someone to 13 work with you being like that 14 you're their employee, I'm not 15 their employee. 16 BY MR. TISI: 17 Q. I understand you're not their 18 employee, but they're an expert locator 19 company, true? They find experts for 20 companies who are looking for experts for 21 litigation, true? 22 A. Again, I don't know exactly 23 what they do. It seems that part of what 24 they do is to try to find experts, but I</p>	<p style="text-align: right;">Page 37</p> <p>1 A. I did that, I took a case 2 that, yeah, they asked me to be a witness 3 on. 4 Q. Well, who asked you? Was it 5 Cornerstone or was it the law firm? 6 A. It was the law firm. 7 Q. Okay. Now, the next case you 8 were involved with was a law firm of Kelley 9 Drye & Warren LLP as an expert 10 witness/statistical consultant in 2015, 11 correct? 12 A. Yes. 13 Q. Okay. The next one was 14 Carlson, Caspers, Vandenburg, Lindquist, 15 and Schuman between 2015 and 2016 as an 16 expert witness/statistical consultant, 17 correct? 18 A. Yes. 19 Q. And then you worked for 20 Haynes & Boone LLP from 2016 to 2017, 21 correct? 22 A. Well, I didn't -- I mean, I 23 don't know if you can say worked for all of 24 these. I don't -- I didn't work for them.</p>

<p style="text-align: right;">Page 38</p> <p>1 I was retained as an expert witness for a 2 case that they were in. 3 Q. In which you were paid, true? 4 A. Oh, yeah, yeah, I was paid. 5 Q. Okay. Now, and you worked 6 for Latham & Watkins between 2017 and the 7 present, true? 8 A. Yes. 9 Q. Okay. And you have been paid 10 by them as well? 11 A. Yeah, I have been paid by 12 them. 13 Q. And you worked for Winston & 14 Strawn between 2016 and the present, true? 15 A. Again, I was retained as an 16 expert witness by them. I don't know if 17 working for them is the right -- I don't 18 think working for them is the right 19 description. 20 Q. Okay. You were retained as 21 an expert witness by all of these law 22 firms, including Winston & Strawn, who is 23 a -- who is a law firm involved in this 24 case. Do you know that?</p>	<p style="text-align: right;">Page 40</p> <p>1 It was kind of confusing, because I 2 was first with Kelley Drye & Warren 3 and I think their party dropped out 4 of the case and then I was retained 5 as an expert witness by Carlson, 6 Caspers. 7 BY MR. TISI: 8 Q. And how many times have you 9 been identified as an expert witness in 10 litigation, sir? 11 A. So does that mean how many 12 times have I provided deposition or 13 something else -- 14 Q. No, how many times have you 15 written a report like you have in this 16 case, which was actually -- where you were 17 actually designated, where you gave 18 permission to the lawyers to say, yes, you 19 can designate me as a witness either by 20 writing a report, in some states, you don't 21 have to write a report, so you just get 22 designated. So if you would give me a 23 sense of how many times you have been 24 designated as an expert on behalf of these</p>
<p style="text-align: right;">Page 39</p> <p>1 A. I didn't know that. 2 Q. Okay. Do you know whether or 3 not you -- can you tell me which of the law 4 firms that are listed here where you 5 actually generated a report which was -- 6 where you were designated as an expert? 7 MS. LEHMAN: I would just, 8 John, to the extent that you were 9 disclosed as a witness, I think 10 that's fine to talk about. To the 11 extent you were not disclosed, that 12 you were merely a consulting 13 expert, I would caution you not to 14 disclose privileged information. 15 THE WITNESS: Okay. So with 16 Latham & Watkins, I was, yeah, 17 disclosed as an expert witness. 18 With Haynes & Boone, I was. 19 Winston & Strawn, I was. And then 20 the previous, if you can scroll 21 back up to the previous page, and 22 with Carlson, Caspers and Kelley 23 Drye & Warren, for both of those, I 24 was disclosed as an expert witness.</p>	<p style="text-align: right;">Page 41</p> <p>1 law firms. 2 A. I believe that is four, 3 except that I'm not sure if the Kelley Drye 4 & Warren and Goodman Neuman Hamilton counts 5 as two separate or just as one. 6 Q. And in each -- 7 A. If it's two separate, then it 8 would count as five. 9 Q. And in each case, you were 10 called upon to provide criticisms of 11 studies or analyses done by the other side 12 in the case, correct? 13 A. No, I don't think that's 14 totally correct. And to the extent that I 15 can talk about them -- 16 Q. Well, tell me -- 17 A. Upon reviewing, again, like, 18 specific papers or abstracts or -- 19 Q. My point is -- 20 A. -- analyses. 21 Q. I'm sorry, we're talking over 22 each other and I didn't mean to do that. 23 My point is this case is not the first time 24 that a law firm has called upon you to</p>

<p style="text-align: right;">Page 42</p> <p>1 criticize a paper that was published by 2 somebody else, true? 3 MS. LEHMAN: Object to form. 4 THE WITNESS: No, I've never 5 heard any -- any case where I have 6 been asked to criticize something 7 and if I was asked to just do that 8 outright, I would not participate. 9 BY MR. TISI: 10 Q. Okay. Well, so let's see 11 if -- maybe the phrase I used is incorrect. 12 This is not first time where you have been 13 called upon to provide an analysis that a 14 paper was flawed and unreliable, true? 15 MS. LEHMAN: Object to form. 16 THE WITNESS: I would still 17 not agree with that statement. 18 And, again, I would not want to 19 work in a case where it was the 20 opinion I was supposed to provide 21 was pre-assumed. 22 BY MR. TISI: 23 Q. Well, I'm not asking you 24 whether you pre-assumed, I'm asking you</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. Well, and those words are 2 actually words that lawyers use all the 3 time. Was that a phrase that was given to 4 you by the lawyers in this case and asked 5 you whether or not this paper was flawed 6 and unreliable? 7 MS. LEHMAN: Object to form. 8 THE WITNESS: No, those words 9 were not given to me by the 10 lawyers. 11 BY MR. TISI: 12 Q. Have you ever -- I'm sorry, 13 go ahead. 14 A. I mean, unreliable is -- 15 reliability is a common term in statistics. 16 Flawed is just a simple English word that 17 something has problems. 18 Q. I'm using the phrase "flawed 19 and unreliable" together the way you used 20 it in this report. Is that a phrase that 21 you have ever used in any of your 22 publications or any of your papers or any 23 of your expert reports before you used it 24 20 times in this case?</p>
<p style="text-align: right;">Page 43</p> <p>1 what your ultimate opinion was. This is 2 not the first case in which you have 3 provided an opinion that a published paper 4 was flawed and unreliable, true? 5 MS. LEHMAN: Object to form. 6 THE WITNESS: I think it's 7 probably the first time that I've 8 used those words, but I would agree 9 that in these cases, there have 10 been papers where I've found 11 problems or issues in a paper. 12 BY MR. TISI: 13 Q. Okay. So you've typically 14 not used the word "flawed and unreliable," 15 except in this case where you've used it 16 over 20 times, true? 17 A. I don't recall for certainty 18 whether I've used those words before or 19 not. 20 Q. Well, that's -- 21 A. But I did, I will say that I 22 found this paper to be particularly flawed 23 and unreliable, yes. So there's a reason I 24 use those words.</p>	<p style="text-align: right;">Page 45</p> <p>1 MS. LEHMAN: Object to form. 2 THE WITNESS: I mean, I don't 3 recall for sure whether I've used 4 that phrase or not. 5 BY MR. TISI: 6 Q. Okay. Let's go back to your 7 invoice, Exhibit No. 3. So if I'm reading 8 this correctly, you met with the 9 Cornerstone team on -- with respect to 10 generating this litigation report on 11 May 20, May 21, May 22, May 26, and May 27, 12 with calls on May 28 and May 29; is that 13 right? 14 A. Yes. 15 Q. Okay. 16 A. That appears to be correct. 17 Q. I'm sorry. 18 A. Yeah, that appears to be 19 correct based on looking here. 20 Q. Who at Cornerstone did you 21 meet with and speak to? 22 A. I don't recall for sure on 23 each occasion who I spoke to, but the 24 people who I met with at Cornerstone</p>

<p style="text-align: right;">Page 46</p> <p>1 regularly were Greg Eastman and I'm 2 blanking right now, I'm sorry, at this 3 moment, I can't think of his name, but I 4 know it will come to me at some point. 5 Q. That's okay. Do you know 6 what their specialty was? Were they 7 administrative? Were they 8 biostatisticians? Were they 9 epidemiologists? What were they? 10 A. I think they're both -- I 11 don't know in detail, I think they're kind 12 of PhDs in economic-related fields. 13 Q. Okay. So now you were 14 telling me before that they provided you 15 with simply administrative support. These 16 were -- these were professional people, 17 true? 18 A. Yeah, I would say they have 19 PhDs and they work at a company, they're 20 professional. 21 Q. Okay. Did they do any 22 research for you? 23 A. In the sense that at times 24 they brought me papers that I requested. I</p>	<p style="text-align: right;">Page 48</p> <p>1 recall doing so. 2 Q. And, in fact, if you go to 3 your bibliography that you've actually used 4 to generate this report, were any of those 5 papers found by Cornerstone, Mr. Eastman, 6 or anybody else? 7 A. I think there were papers 8 that I asked, like, them to get for me on 9 my behalf, yes. 10 Q. Did they, for example, do a 11 research on multiple imputation and whether 12 or not including outcomes as part of the 13 imputation model was appropriate or not 14 appropriate? Did they do things like that? 15 MS. LEHMAN: Object to form. 16 THE WITNESS: I mean, I don't 17 know if they did them, but not at 18 my direction. They do -- it was 19 not in discussion with me, it was 20 not at my request, what they did. 21 What's in my report is my own words 22 and of my opinions. 23 BY MR. TISI: 24 Q. Okay. So now looking back on</p>
<p style="text-align: right;">Page 47</p> <p>1 asked them to generate a Google trends 2 figure for me. 3 Q. Okay. And that's the table 4 that's in your report, correct? 5 A. It's not a table, it's a 6 figure, it's a graph, a plot. 7 Q. Fine. So that wasn't your 8 graph, that was a graph that they generated 9 for you, correct? 10 MS. LEHMAN: Object to form. 11 THE WITNESS: I take 12 responsibility for it. It's my 13 graph. It was generated at my 14 request, and yeah. 15 BY MR. TISI: 16 Q. Have you ever used a Google 17 graph like that in any of your published 18 work? 19 MS. LEHMAN: Object to form. 20 BY MR. TISI: 21 Q. Have you used Google trends 22 in any of your published work? 23 A. I can't say with 100 percent 24 certainty that I haven't, but I don't</p>	<p style="text-align: right;">Page 49</p> <p>1 your billing statement, May 20, 2024, you 2 met with the lawyers and read the paper, 3 although you might not have read the whole 4 thing, I understand that, on the 20th. 5 When do you think you actually read the 6 whole paper cover to cover? 7 MS. LEHMAN: Object to form. 8 THE WITNESS: I don't know if 9 I ever read it from start to 10 finish, I mean, it's just not the 11 way people tend to approach 12 academic papers. 13 BY MR. TISI: 14 Q. Okay. 15 A. So but -- 16 Q. Well, when was it that you -- 17 A. By the time I had written my 18 report, I was completely familiar with the 19 paper. 20 Q. Okay. Well -- 21 A. Obviously, there were parts 22 that I focused on more than others. 23 Q. So it looks like you actually 24 prepared notes for your report on the 22nd,</p>

<p style="text-align: right;">Page 50</p> <p>1 do you see that, you spent ten hours?</p> <p>2 A. Right. I spent ten hours</p> <p>3 reviewing the paper preparing notes for the</p> <p>4 report and meeting with the Cornerstone</p> <p>5 team.</p> <p>6 Q. Right. Ten hours on the</p> <p>7 22nd. Had you formed your opinions by then</p> <p>8 that the paper was flawed and unreliable?</p> <p>9 A. I don't recall to what extent</p> <p>10 I formed my opinions. By then, I was</p> <p>11 forming my opinions in the process of</p> <p>12 writing the report.</p> <p>13 Q. Okay. When do you think in</p> <p>14 this continuum from May 20 through May 28,</p> <p>15 when you actually filed your report, in</p> <p>16 those eight days, did you finally come to</p> <p>17 your opinions that you were prepared to</p> <p>18 offer that are reflected in your report,</p> <p>19 Exhibit 1?</p> <p>20 MS. LEHMAN: Object to form.</p> <p>21 Asked and answered.</p> <p>22 THE WITNESS: I wrote my</p> <p>23 report over this time and when the</p> <p>24 report was written, then my</p>	<p style="text-align: right;">Page 52</p> <p>1 aspects of what is flawed and unreliable</p> <p>2 about this paper --</p> <p>3 Q. So, let me be clear -- so let</p> <p>4 me be clear. I understand you think that</p> <p>5 multiple, they're flawed and unreliable in</p> <p>6 multiple areas, true?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. The first time that</p> <p>9 you have come to the conclusion that one</p> <p>10 area was flawed and unreliable was when?</p> <p>11 MS. LEHMAN: Object to form.</p> <p>12 THE WITNESS: I don't recall</p> <p>13 that.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Would it have been when you</p> <p>16 started writing your report on the 23rd?</p> <p>17 A. I probably had an idea of</p> <p>18 something by the time I started writing my</p> <p>19 report.</p> <p>20 Q. Okay. So just to be clear,</p> <p>21 okay, you knew, you got this report, you</p> <p>22 got the O'Brien (2024) from the lawyers on</p> <p>23 the 20th, you met with the lawyers on the</p> <p>24 20th, and you had come to conclusion that</p>
<p style="text-align: right;">Page 51</p> <p>1 opinions were completed.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Well, it says your report</p> <p>4 was -- you were writing your report on the</p> <p>5 23rd. Do you see that? And then you were</p> <p>6 revising your report on the 25th and the</p> <p>7 26th and the 27th and the 28th. Was the</p> <p>8 report actually written in a draft form on</p> <p>9 the 23rd?</p> <p>10 A. I mean, I think I may have</p> <p>11 been a little loose with my language here</p> <p>12 between what constitutes report writing,</p> <p>13 report editing, revising report. The</p> <p>14 process was preparing my report the whole</p> <p>15 way through, so at times, I might be</p> <p>16 writing a paragraph and I might be editing</p> <p>17 another piece.</p> <p>18 Q. I understand. I'm trying to</p> <p>19 get a sense, Doctor, as to when you first</p> <p>20 developed your opinion that this paper was</p> <p>21 flawed and unreliable and started -- for</p> <p>22 the purpose of generating your litigation</p> <p>23 report?</p> <p>24 A. I mean, there are different</p>	<p style="text-align: right;">Page 53</p> <p>1 the paper was flawed and unreliable to</p> <p>2 write a litigation report beginning on the</p> <p>3 23rd, correct?</p> <p>4 MS. LEHMAN: Object to form.</p> <p>5 Misstates testimony.</p> <p>6 THE WITNESS: I mean, again, I</p> <p>7 don't recall what I wrote on</p> <p>8 5/23 exactly, but between May 20</p> <p>9 and May 23rd, I mean, this was, to</p> <p>10 review this paper was a compressed</p> <p>11 timeline, so I spent a lot of time</p> <p>12 on the 21st and 22nd reviewing this</p> <p>13 paper. So I would be -- that would</p> <p>14 have been plenty of time for me to</p> <p>15 start -- certainly be aware of</p> <p>16 problems with the paper.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Right. So you spent about 18</p> <p>19 hours, including meeting with the lawyers</p> <p>20 and the company that actually found you for</p> <p>21 the lawyers, between the 20th and starting</p> <p>22 writing the paper on the 22nd. You wrote</p> <p>23 the report on the 22nd, true?</p> <p>24 A. I'm sorry, repeat that again.</p>

<p style="text-align: right;">Page 54</p> <p>1 Q. Yeah. I said, just so that 2 we're clear, okay, you did not receive this 3 paper in the normal course of your 4 research, this paper was provided to you by 5 the lawyers and the company that was 6 retained by the lawyers to locate you on 7 the 20th, true?</p> <p>8 A. I received the paper from 9 them and I also downloaded it on the 20th.</p> <p>10 Q. Right. And you spent about 11 18 hours, after meeting with the lawyers 12 and Cornerstone, the company that locates 13 experts for lawyers, in two days between 14 the 20th and the 22nd, true?</p> <p>15 MS. LEHMAN: Object to form.</p> <p>16 THE WITNESS: I don't want to 17 categorize what Cornerstone does as 18 part of the question. I mean --</p> <p>19 BY MR. TISI: --</p> <p>20 Q. Fine.</p> <p>21 A. -- Cornerstone contacted me. 22 What they do --</p> <p>23 Q. So let's be clear --</p> <p>24 A. -- their business is, like,</p>	<p style="text-align: right;">Page 56</p> <p>1 a reliable association between talcum 2 powder use and ovarian cancer. Getting to 3 causation is a much higher bar than that, 4 and I don't think they've reliably got to 5 the lower bar.</p> <p>6 Q. Okay. In this one paper, you 7 haven't looked at any other papers -- I 8 know you looked at some other papers by 9 O'Brien and colleagues, but you didn't look 10 at any of the other case control or cohort 11 studies that were generated in this 12 litigation for the past 50 years, did you?</p> <p>13 MS. LEHMAN: Object to form.</p> <p>14 THE WITNESS: I did look at 15 some of them. I looked at -- I 16 looked in particular at one or two 17 meta-analyses in particular of the 18 case controls and one that combined 19 case control and cohort. And I 20 don't recall if I looked at any of 21 the individual studies, but I 22 looked at the meta-analyses that 23 summarized each of the studies. 24</p>
<p style="text-align: right;">Page 55</p> <p>1 if we can leave it out of it.</p> <p>2 Q. Then I'll leave it out. I'll 3 leave it out. Let me rephrase the 4 question, sir. Okay. You were provided a 5 copy of O'Brien (2024) on the 20th. You 6 met with the lawyers on the 20th. And by 7 the 22nd, you had come to the conclusion in 8 some fashion that the paper was flawed and 9 unreliable?</p> <p>10 A. I don't know that I had in my 11 head the words "flawed and unreliable" on 12 the 22nd. I don't have that strong a 13 memory. But by the end of the 22nd, I 14 would be pretty sure that I was aware by 15 that time that there were problems with the 16 paper.</p> <p>17 Q. Okay. You didn't do a 18 comprehensive evaluation or assessment of 19 the causation question, did you? In other 20 words, whether or not talc was -- causes 21 ovarian cancer, did you?</p> <p>22 A. I did not do that -- I 23 didn't -- I was evaluating for a lower bar 24 of whether or not there was an association,</p>	<p style="text-align: right;">Page 57</p> <p>1 BY MR. TISI:</p> <p>2 Q. Okay. But just to be clear, 3 okay, you have not done a comprehensive 4 review of all of the data to determine 5 whether or not as a whole talc is 6 associated with or caused by -- causes 7 ovarian cancer, correct? You just looked 8 at this paper, true?</p> <p>9 MS. LEHMAN: Object to form.</p> <p>10 THE WITNESS: No, I didn't 11 just look at this paper. I looked 12 at the papers by O'Brien too and I 13 also looked at meta-analyses 14 studies that considered --</p> <p>15 BY MR. TISI:</p> <p>16 Q. Right, and that was a bad 17 question. Let me rephrase the question. 18 Okay.</p> <p>19 Your task in this case was 20 not to offer an opinion as to whether or 21 not talc causes ovarian cancer, your task 22 was to comment on the methods and 23 conclusions in O'Brien (2024), correct?</p> <p>24 MS. LEHMAN: Object to form.</p>

<p style="text-align: right;">Page 58</p> <p>1 THE WITNESS: My task was to</p> <p>2 independently review O'Brien (2024)</p> <p>3 and the methods used in that.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. And you had come, just</p> <p>6 to be clear, you had come to the conclusion</p> <p>7 that there were serious methodologic issues</p> <p>8 in three days between the time you met the</p> <p>9 lawyers and the time you started preparing</p> <p>10 your report, true?</p> <p>11 MS. LEHMAN: Object to form.</p> <p>12 THE WITNESS: I think that</p> <p>13 would be typical for academic</p> <p>14 review of a paper that you would</p> <p>15 generate your views within that</p> <p>16 period of time, especially if you</p> <p>17 spend the amount of hours that I</p> <p>18 did.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay. Now, in the three days</p> <p>21 before you -- you raised numerous questions</p> <p>22 about what the authors of -- the NIH</p> <p>23 scientists who actually drafted this paper,</p> <p>24 what they did, how they did it, throughout</p>	<p style="text-align: right;">Page 60</p> <p>1 Q. Why did you think it would be</p> <p>2 inappropriate to ask any of the authors, if</p> <p>3 you had any questions about the methodology</p> <p>4 that they used, why they did what they did,</p> <p>5 why do you think it would be inappropriate</p> <p>6 to actually call them and say I have some</p> <p>7 questions, let me know.</p> <p>8 A. Because I was -- it would be</p> <p>9 inappropriate in the same way that if I was</p> <p>10 reviewing an academic paper for a journal,</p> <p>11 it would be a really terrible thing to</p> <p>12 contact one of the authors to start asking</p> <p>13 them questions about the paper. That would</p> <p>14 be totally unacceptable.</p> <p>15 Q. Why is that unacceptable?</p> <p>16 Tell me why.</p> <p>17 A. Because of confidentiality of</p> <p>18 review, because it means that the reviewer</p> <p>19 can be influenced by opinions.</p> <p>20 Q. Well, if you look at -- if</p> <p>21 you look at page 14 of Exhibit No. 8, which</p> <p>22 is the O'Brien study, she lists herself as</p> <p>23 the O'Brien -- as the corresponding author</p> <p>24 and she gives her email address. Do you</p>
<p style="text-align: right;">Page 59</p> <p>1 your report, correct? You had some</p> <p>2 questions and concerns, true?</p> <p>3 MS. LEHMAN: Object to form.</p> <p>4 THE WITNESS: I certainly have</p> <p>5 concerns about the methods reported</p> <p>6 in the paper.</p> <p>7 BY MR. TISI:</p> <p>8 Q. In any of the three days</p> <p>9 between the time you were contacted by the</p> <p>10 lawyers and the time you started drafting</p> <p>11 your report, did you reach out to any of</p> <p>12 the NIH authors to ask them why they did</p> <p>13 what they did?</p> <p>14 MS. LEHMAN: Object to form.</p> <p>15 THE WITNESS: No, I think that</p> <p>16 would be inappropriate.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Well, Dr. O'Brien is listed</p> <p>19 as the corresponding author on this study,</p> <p>20 correct?</p> <p>21 A. I would have to double-check</p> <p>22 that. I know she's the first author. I</p> <p>23 didn't check if she's the corresponding</p> <p>24 author.</p>	<p style="text-align: right;">Page 61</p> <p>1 see that?</p> <p>2 A. Okay. I think it's pretty</p> <p>3 common in paper -- I'm going to page 8 now,</p> <p>4 but, yeah, it's pretty common for there to</p> <p>5 be a corresponding author on a paper that</p> <p>6 provides their email address.</p> <p>7 Q. And why do they do that,</p> <p>8 Dr. Kornak?</p> <p>9 A. Because if people are</p> <p>10 interested in the research, they can</p> <p>11 contact them.</p> <p>12 Q. And you weren't really</p> <p>13 interested in the research, were you? You</p> <p>14 didn't contact them at all at any time,</p> <p>15 have you?</p> <p>16 MS. LEHMAN: Object to form.</p> <p>17 Argumentative. Asked and answered.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Let me rephrase the question.</p> <p>20 Dr. Kornak, between the time the lawyers</p> <p>21 met you on the 20th and today, have you</p> <p>22 ever reached out to the NIH scientists to</p> <p>23 ask them any questions about the research</p> <p>24 that they did?</p>

<p style="text-align: right;">Page 62</p> <p>1 MS. LEHMAN: Object to form.</p> <p>2 THE WITNESS: I have not.</p> <p>3 Again, I would not think it's</p> <p>4 appropriate.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Okay. Even though Katie</p> <p>7 O'Brien lists herself as the corresponding</p> <p>8 author, and you have no reason to believe</p> <p>9 that she would not have answered your</p> <p>10 questions, right?</p> <p>11 MS. LEHMAN: Objection. Asked</p> <p>12 and answered.</p> <p>13 THE WITNESS: I don't know</p> <p>14 Katie O'Brien. I don't know how</p> <p>15 responsive she is to emails. I</p> <p>16 know that whenever I'm reviewing</p> <p>17 papers, I never contact the</p> <p>18 corresponding author. I don't let</p> <p>19 them know even after the fact</p> <p>20 whether or not I reviewed their</p> <p>21 paper. I consider that to be</p> <p>22 confidential --</p> <p>23 BY MR. TISI:</p> <p>24 Q. That's a different question.</p>	<p style="text-align: right;">Page 64</p> <p>1 you never contacted them to ask how they</p> <p>2 performed the quantitative bias analysis</p> <p>3 reflected in the four scenarios in Table 2</p> <p>4 of the O'Brien (2024) study, correct?</p> <p>5 MS. LEHMAN: Object to form.</p> <p>6 Asked and answered.</p> <p>7 THE WITNESS: What I know of</p> <p>8 about how they performed this study</p> <p>9 is what they reported within their</p> <p>10 paper. And it's academically</p> <p>11 expected that when you describe an</p> <p>12 experiment within a paper and the</p> <p>13 analysis that you performed that</p> <p>14 you provide enough information for</p> <p>15 that to be reproducible.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Do you know -- so you never</p> <p>18 contacted them and asked them, for example,</p> <p>19 why did you do multiple imputation as</p> <p>20 opposed to individual imputation as a</p> <p>21 method? You never asked that question, did</p> <p>22 you?</p> <p>23 MS. LEHMAN: Object to form.</p> <p>24 Asked and answered.</p>
<p style="text-align: right;">Page 63</p> <p>1 A. -- and that I reviewed this.</p> <p>2 Q. That's a different question.</p> <p>3 I'm not asking you to reach out to somebody</p> <p>4 during the peer-review process. This paper</p> <p>5 was published in a peer-reviewed journal on</p> <p>6 May 15, right? You had some questions</p> <p>7 about this paper and why they did what they</p> <p>8 did. There is a corresponding author on</p> <p>9 this paper. Did you contact them after the</p> <p>10 paper had been published, after all the</p> <p>11 criticisms and all the information about</p> <p>12 this study had been put out there for the</p> <p>13 world to see it, did you ever contact them</p> <p>14 with any of the concerns you raise in your</p> <p>15 litigation report?</p> <p>16 MS. LEHMAN: Object to form.</p> <p>17 Asked and answered.</p> <p>18 THE WITNESS: I did not and I</p> <p>19 don't think it's appropriate if my</p> <p>20 task is to independently review a</p> <p>21 paper to seek out additional</p> <p>22 opinions.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Okay. So am I correct to say</p>	<p style="text-align: right;">Page 65</p> <p>1 THE WITNESS: I didn't ask</p> <p>2 that question. I would have no</p> <p>3 interest in asking that question,</p> <p>4 because I don't think it's relevant</p> <p>5 to my opinions. And -- okay --</p> <p>6 BY MR. TISI:</p> <p>7 Q. I'm sorry, I didn't mean to</p> <p>8 interrupt. Finish your sentence, please.</p> <p>9 A. I'm fine stopping there.</p> <p>10 Q. Okay. For example, at the</p> <p>11 end of your report, you had questions about</p> <p>12 whether or not the decision to -- some of</p> <p>13 the decisions were made to do multiple</p> <p>14 imputation were done a priori or whether it</p> <p>15 was done after the study had begun. Do you</p> <p>16 remember those questions?</p> <p>17 MS. LEHMAN: Object to form.</p> <p>18 THE WITNESS: I would like to</p> <p>19 look specifically at those</p> <p>20 questions. If you want to go to</p> <p>21 that section of the report and</p> <p>22 let's do that and discuss it.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Sure. In your report, you</p>

<p style="text-align: right;">Page 66</p> <p>1 have a section entitled "The lack of 2 prespecified analysis renders the authors' 3 conclusions flawed and unreliable." 4 Do you see that? 5 A. Yes, I recall that, I'm just 6 going to it now, but I recall that section, 7 yes. 8 Q. So you don't know whether or 9 not their methods were set out a priori, do 10 you, true? 11 MS. LEHMAN: Object to form. 12 THE WITNESS: If they had a 13 prespecified analysis plan, it 14 should be specified, they should be 15 specifying that within the paper. 16 BY MR. TISI: 17 Q. But they -- you didn't 18 contact them, this is a criticism that you 19 made of these authors with no knowledge, 20 you didn't call them and see whether -- in 21 fact, it could have been suggested by the 22 peer reviewers, correct? 23 MS. LEHMAN: Object to form. 24 THE WITNESS: Okay. I don't</p>	<p style="text-align: right;">Page 68</p> <p>1 specific prospective data to Appendix 2 and 2 you do that in paragraph 29 of your 3 litigation report, true? 4 A. Yes, I recall that. I'm 5 going to the paragraph now and I do recall 6 that and I firmly stand by that statement. 7 Q. And you don't know why they, 8 quote, "relegated" it to the appendix, do 9 you? 10 A. I mean, I don't know what's 11 in the authors' mind other than what 12 they've written in their paper. 13 Q. And you didn't ask them, did 14 you? 15 MS. LEHMAN: Object to form. 16 Asked and answered. 17 THE WITNESS: I didn't. I 18 don't think that would be 19 appropriate. 20 BY MR. TISI: 21 Q. Well, there are plenty of 22 ways in which scientists actually raise 23 questions about academic papers, true? 24 A. Sorry, repeat the question</p>
<p style="text-align: right;">Page 67</p> <p>1 want to speculate as what the peer 2 reviewers may or may not have said. 3 BY MR. TISI: 4 Q. But you are rendering an 5 opinion here about that there was not a 6 prespecified analysis and you don't know 7 the answer to that question, do you? 8 MS. LEHMAN: Object to form. 9 Asked and answered. 10 THE WITNESS: Well, everything 11 in this paper indicates a lack of a 12 prespecified analysis plan. There 13 are arbitrary choices of 14 proportions that are corrected. 15 There are arbitrary levels of 16 recall bias that are performed. 17 None of those are justified within 18 the paper. That lack of 19 justification indicates a lack of a 20 prespecified analysis plan. 21 BY MR. TISI: 22 Q. Now, you claim, for example, 23 that they relegated, and that's your term, 24 you relegated a baseline analysis of purely</p>	<p style="text-align: right;">Page 69</p> <p>1 again. I didn't catch it. 2 Q. There are plenty of ways in 3 the world of science where scientists 4 exchange views about the relative merit -- 5 MS. LEHMAN: Chris, you broke 6 up. I'm not sure I got the last of 7 that question. 8 BY MR. TISI: 9 Q. Yeah. There are plenty of 10 ways in which scientists raise questions 11 about research in the normal course of 12 scientific endeavor, true? 13 A. Correct. 14 Q. All right. One of the ways 15 you can do it is like we have been 16 suggesting is contact the authors and ask 17 questions, but let's put that aside for a 18 minute. You could write a letter to the 19 editor of this journal, true? You've seen 20 that done. 21 A. You could, if that was 22 something you wanted to pursue, you could 23 write a letter to the editor. It's not 24 something that I do and I don't know of any</p>

<p style="text-align: right;">Page 70</p> <p>1 of -- many people that do that. 2 Q. Well, you could write a 3 letter to the authors and ask the authors 4 formally to respond to your criticisms, 5 true? In fact, you've seen that done in 6 this case with O'Brien (2020) where there 7 is authors including, for example, Ken 8 Rothman wrote a letter to the editor and 9 O'Brien explained herself, true? 10 MS. LEHMAN: Object to form. 11 Object to counsel testifying. 12 THE WITNESS: I did see a 13 letter written by those two 14 authors. I don't know what their 15 motives were for doing that and I 16 don't want to speculate on that, 17 but -- 18 BY MR. TISI: 19 Q. Right, but -- 20 A. But as academics, we don't 21 usually go out trying to publicly denounce 22 what other people are doing in letters to 23 the editor. 24 Q. Nobody is asking for public</p>	<p style="text-align: right;">Page 72</p> <p>1 litigation report for which you charged 2 over \$50,000, true? 3 MS. LEHMAN: Object to form. 4 THE WITNESS: The only place I 5 have commented on this paper is 6 within this report. 7 BY MR. TISI: 8 Q. Okay. And you were paid 9 \$50,000 to do it, true? 10 MS. LEHMAN: Object to form. 11 THE WITNESS: My invoice is 12 there, I forget the exact amount, 13 but I think that is it. 14 BY MR. TISI: 15 Q. Let's look at it. The number 16 is \$50,000, correct? 17 A. 50,400, yeah. 18 Q. All right. And since that 19 time, have you also spent time with 20 Ms. Davidson, perhaps other lawyers or 21 Cornerstone working on this project? 22 A. I have spent more time 23 reviewing materials, preparing for 24 deposition.</p>
<p style="text-align: right;">Page 71</p> <p>1 denouncement, okay? If you have questions 2 about research, you could write a letter to 3 the journal and ask the authors to clarify 4 what they did, and you didn't do that here, 5 did you? 6 MS. LEHMAN: Objection. Asked 7 and answered. 8 THE WITNESS: I did not write 9 a letter to the editor. I did not 10 email the authors. I did not think 11 those things were appropriate for 12 me to do. I had a certain amount 13 of time that I wanted to 14 independently review the paper, 15 O'Brien (2024), and that's what I 16 did. And my opinions about the 17 paper are what they are and if I 18 had spoken to authors about that, 19 it wouldn't change my opinions 20 about what's in the paper. 21 BY MR. TISI: 22 Q. All right. And the only 23 place that you have ever expressed your 24 opinions about this paper is in a</p>	<p style="text-align: right;">Page 73</p> <p>1 Q. How many hours? 2 A. I would estimate it has been, 3 I don't know, somewhere between 50 and 100 4 hours. 5 Q. Fifty and 100 hours in 6 addition? 7 A. Yeah, I think so. 8 Q. Okay. And so at your rate of 9 \$700 an hour, what would that be? 10 A. If it was 100 hours, it would 11 be 70,000. 12 Q. Okay. So to be fair and just 13 to be clear, the only place you have 14 ever -- I mean, the opinions you offer here 15 as a scientist about a particular paper, 16 the opinions you offer here are pretty 17 strong opinions, true? 18 A. Yeah, I stand by my opinions. 19 Q. Okay. But they're pretty 20 strong, these aren't peripheral kinds of 21 criticisms, these are really strong 22 methodologic allegations you make on these 23 authors and their methods about how they 24 conducted this study; is that true?</p>

<p style="text-align: right;">Page 74</p> <p>1 A. They are appropriate 2 criticisms. 3 Q. Okay. They're strong 4 criticisms. If you got a criticism -- 5 A. No, no, I don't -- sorry, I 6 don't want to interrupt you. Sorry, go 7 ahead. 8 Q. Well, then let me ask you 9 this question, if you got a criticism like 10 this of one of your papers, would you 11 consider it to be a strong criticism? 12 MS. LEHMAN: Object to form. 13 THE WITNESS: I mean, I would 14 consider it to be a criticism. 15 What -- the way you would exactly 16 draw the line between strong and 17 not strong in academic criticism, I 18 don't know exactly how to specify, 19 but I certainly criticize and think 20 there are problems with the 21 approach. 22 BY MR. TISI: 23 Q. Well, in this report, I'm 24 going to say you used the word, the phrase</p>	<p style="text-align: right;">Page 76</p> <p>1 analysis. I just want to be clear, 2 I'm not criticizing individuals. 3 BY MR. TISI: 4 Q. I understand. So -- I'm 5 sorry -- you are making a very strong 6 criticism in very strong terms of the 7 methods used by these NIH scientists in 8 publishing this peer-reviewed paper, true? 9 MS. LEHMAN: Object to form. 10 THE WITNESS: I'm criticizing 11 the methods they use. I'm not 12 going to characterize it with the 13 word "strong," that -- 14 BY MR. TISI: 15 Q. Well, you used the words 16 "flawed," "unreliable," "vacuous," 17 "contrived," I mean, those are your words 18 in your report, true? 19 A. But you're just taking -- the 20 words may be in my report in some way, but 21 you're taking them out of context and -- 22 Q. I understand but those are -- 23 I'm sorry. I'm talking over you. I don't 24 mean to. Those are words that you use to</p>
<p style="text-align: right;">Page 75</p> <p>1 "flawed and unreliable" over 20 times. And 2 if you go to paragraph 74 of your report, 3 you call this analysis contrived, vacuous, 4 and overstating. 5 Do you see that? 6 MS. LEHMAN: Object to form. 7 THE WITNESS: I think those 8 are used in the paragraph, but 9 they're not used as you stated 10 them. 11 BY MR. TISI: 12 Q. Okay. My point is, Doctor, 13 and I'm really trying to get to 20,000 per 14 year. Okay. This is a very strong report 15 where you use very strong language and very 16 strong criticisms of these NIH scientists 17 who published a paper in a peer-reviewed 18 journal, true or not true? 19 A. I am not criticizing -- 20 MS. LEHMAN: Object to form. 21 THE WITNESS: -- the 22 scientists. I'm criticizing the 23 science of the paper. I'm 24 criticizing the biostatistical</p>	<p style="text-align: right;">Page 77</p> <p>1 describe various aspects of their analysis, 2 true? 3 MS. LEHMAN: Object to form. 4 Asked and answered. 5 THE WITNESS: I would need to 6 go through each sentence one by one 7 to sort of explain to you how that 8 word is being used, and I'm happy 9 to do that if you want to walk 10 through each of the sentences -- 11 BY MR. TISI: 12 Q. We're going to. 13 A. -- rather than your general 14 statement on those words. So we can -- 15 Q. We're going to. But let me 16 ask you as an overall thing. If you had 17 received from one of your colleagues a 18 report like the one that you drafted, you 19 drafted in this case about one of your 20 papers, would you consider that to be a 21 pretty strong rebuke of your research? 22 MS. LEHMAN: Objection. Asked 23 and answered. 24 THE WITNESS: I'm not going to</p>

20 (Pages 74 - 77)

<p style="text-align: right;">Page 78</p> <p>1 use the word "strong." I mean, 2 again -- 3 BY MR. TISI: 4 Q. Okay. Then let's take the 5 word -- 6 A. I take criticism, sometimes 7 it hurts, but overall, it tends to be 8 constructive in academia for the positive 9 even if it hurts sometimes. 10 Q. Okay. But this isn't an 11 academic report, is it? This is a 12 litigation report, true? 13 A. I thought we were talking 14 about the paper as a report, sorry -- 15 Q. I'm asking you -- 16 A. A criticism of a report, 17 that's what we're talking about. Like, you 18 were talking about criticism of a report 19 that I had wrote of some kind. I assumed 20 you were talking about the paper, so I just 21 want to clarify. 22 Q. Okay. If you had received -- 23 let's take it in ones, right? If you had 24 received a criticism like you prepared of</p>	<p style="text-align: right;">Page 80</p> <p>1 this case, has it? 2 A. I don't know who has and who 3 hasn't seen my report. 4 Q. You haven't presented it. 5 You haven't sent it to anybody outside of 6 this case, have you? 7 A. No, I think I shouldn't from 8 a confidentiality perspective and that's 9 another reason I don't think I should have 10 contacted the authors of the paper or 11 anything like that. I think that would be 12 inappropriate. 13 Q. Nothing prevents you from 14 speaking to your students at UCSF and 15 saying, you know, I'm going to illustrate 16 to you the kinds of methodologic flaws that 17 can come from an improper biostatistic 18 analysis and let me use this paper as an 19 example. You've never done that, have you? 20 A. Well, I mean I think it's -- 21 first of all, a physical impossibility, 22 because I was retained on this case on 23 May 20 and, you know, I haven't been doing 24 any teaching since then, I haven't been in</p>
<p style="text-align: right;">Page 79</p> <p>1 one of your papers, would you consider that 2 to be serious? 3 MS. LEHMAN: Objection. Asked 4 and answered. 5 THE WITNESS: I mean, I don't 6 know why you're looking for a 7 qualifying word here, but if 8 there's criticism, I take 9 criticism. Sometimes it hurts. 10 That's a feeling that you have 11 whenever you're criticized for your 12 academic work or other work. But, 13 in general, I find that it's a 14 positive thing to learn from 15 criticism. 16 BY MR. TISI: 17 Q. Okay. Now, your report was 18 not intended to engage these authors in an 19 academic exercise, was it, it was a 20 litigation report, true? 21 A. Yes, it's a litigation 22 report, yeah. 23 Q. And it has not been presented 24 to any scientist outside of the lawyers in</p>	<p style="text-align: right;">Page 81</p> <p>1 touch with students. But I would also 2 still respect the confidentiality aspect 3 that I don't know exactly where the line is 4 as to when you're breaking confidentiality 5 or not, so I err on the side of safety and, 6 yes, I don't discuss with anyone or 7 anything. So if it's a paper -- why would 8 I choose -- why would I not just go to 9 another paper that is completely unrelated 10 and I don't take any risk of breaking 11 confidentiality. That would be my 12 thinking. 13 Q. And -- 14 MS. LEHMAN: And Chris, Chris, 15 I don't mean to interrupt you, but 16 when you get to a good stopping 17 point, can we take a bathroom 18 break? 19 BY MR. TISI: 20 Q. Sure. No problem. So you 21 think because you were retained as an 22 expert in litigation, that removes you from 23 commenting on this paper in any scientific 24 form, is that what you're saying?</p>

<p style="text-align: right;">Page 82</p> <p>1 A. No, I'm not saying that. I 2 think I said clearly before that I don't 3 know where the line is and so I opt to 4 respect confidentiality as much as 5 possible. 6 Q. Did you ask? Did you ask the 7 lawyers and say, you know, this paper is 8 particularly egregious and I want to 9 present it out there so that nobody relies 10 on this paper? You've not done that, have 11 you? 12 MS. LEHMAN: And I'm just 13 going to object and instruct 14 Dr. Kornak that to the extent he's 15 talking about communications with 16 the lawyers, he can talk about 17 facts and data that he considered 18 in rendering the report, but 19 otherwise, I'm going to instruct 20 that communications with the 21 lawyers are privileged and 22 confidential. 23 MR. TISI: What they say to 24 him is privileged and confidential.</p>	<p style="text-align: right;">Page 84</p> <p>1 date. 2 Q. Is there anything that needs 3 to be added to it in order for us to fully 4 understand your professional background and 5 experience particularly as it relates to 6 the issues in this case? 7 A. I don't think so. 8 Q. Okay. Are you an 9 epidemiologist? 10 A. No, I'm a biostatistical 11 expert, but I have a lot of experience in 12 epidemiological areas. 13 Q. What is the difference 14 between a biostatistician and an 15 epidemiologist? 16 A. I think it's a difficult 17 question to fully answer, but the 18 biostatistician is generally more focused 19 on the computation methods for analyzing 20 data and for understanding data whereas the 21 epidemiologist tends to be more focused on 22 kind of typically a more specific clinical 23 area and have an interest there. 24 Q. The epidemiologist is more</p>
<p style="text-align: right;">Page 83</p> <p>1 Have you asked anyone if you can 2 criticize this outside of 3 litigation? 4 THE WITNESS: I'm just going 5 to repeat my answer, I err on the 6 side of confidentiality, so I 7 was -- did not talk to additional 8 people. 9 MR. TISI: Okay. All right. 10 Let's take a quick break. 11 THE WITNESS: Thank you. 12 - - - - - 13 (A recess was taken at this time.) 14 - - - - - 15 BY MR. TISI: 16 Q. All right. Dr. Kornak, we 17 have been provided with your CV, which I've 18 had marked as Exhibit No. 2. If you pull 19 that out, please. 20 A. Yes. 21 Q. Does your CV accurately 22 reflect your professional experience? 23 A. I would say to a large 24 extent, yes, a couple of things are out of</p>	<p style="text-align: right;">Page 85</p> <p>1 involved with the actual interpretation of 2 the data and putting it in context with 3 what is -- with the body of medical and 4 scientific literature, true? 5 A. I wouldn't say they're more 6 involved with the interpretation of the 7 data. They're definitely, I would agree, 8 that within a particular clinical area, if 9 that's where they're working, they would be 10 more knowledgeable on placing the research 11 in that area, but interpretation of data is 12 very much biostatistical. 13 Q. Let me ask you this way. If 14 an epidemiologist and biostatistician are 15 cowriting an original epidemiologic study 16 either, for example, a case control study 17 or a cohort study, what would the typical 18 respective roles of the biostatistician be 19 in relationship to the epidemiologist? 20 A. I would say that really 21 depends and can vary quite a lot. I mean, 22 it varies a lot. 23 Q. Well, give me a sense, give 24 me a sense of the range? I mean, if you</p>

<p style="text-align: right;">Page 86</p> <p>1 were explaining to your students, and let's 2 say you were co-teaching with an 3 epidemiologist, how would you define your 4 respective roles in writing a paper? 5 A. So it can range from, I'm 6 being very loose here, but it can range 7 from as a biostatistician that it could be 8 a very straightforward consulting role on a 9 project where there's data that has already 10 been collected and needs to be analyzed and 11 the statistician would take that data and 12 analyze it appropriately and then help with 13 the writing of the paper maybe in the 14 results section and the methods section and 15 so on. That's kind of down at one end. At 16 the upper end, it can be that the 17 statistician is right there helping with 18 the experimental design, helping with 19 thinking about how to recruit individuals 20 with minimal bias. All of those pieces 21 that I said that they would do in a 22 consulting role, but they would be much 23 more involved and interested in the 24 research on their own behalf too.</p>	<p style="text-align: right;">Page 88</p> <p>1 A. Imaging and non-imaging 2 perspective. 3 Q. Right, but the primary focus, 4 and you may have touched on issues relating 5 to, for example, breast cancer, but your 6 primary focus was on imaging for tumors, et 7 cetera, correct? 8 MS. LEHMAN: Object to form. 9 THE WITNESS: I don't think 10 touched on is a good description of 11 sort of my involvement with breast 12 cancer. 13 BY MR. TISI: 14 Q. Well, have you ever, for 15 example, done a study that studies risk 16 factors for -- where the primary goal of 17 the study was to discover risk factors for 18 breast cancer? 19 A. Yes. 20 Q. Okay. How about ovarian 21 cancer, have you ever published in the area 22 of ovarian cancer? 23 A. I don't recall any of my 24 publications being specifically ovarian</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. So would it be fair to say 2 that, generally speaking, the 3 epidemiologist as opposed to the 4 biostatistician would be more concerned 5 with being specific to this case how to 6 deal with issues of recall bias? 7 A. No, I don't agree. 8 Q. Okay. All right. Now, 9 looking at your CV read as a whole, and I 10 did read it, I can't say I understood every 11 word, but I did read it, I would say it 12 seems the focus in your academic work is 13 with imaging; is that correct? 14 A. I think there are multiple 15 areas that are and have been the focus of 16 my research. Imaging has certainly always 17 been there. Medical imaging specifically. 18 With applications, I mean, breast cancer 19 has been a sort of central theme of my 20 research over many years, in particular 21 related to medical imaging too, but also 22 beyond medical imaging and the study of 23 dementia as well. 24 Q. Okay.</p>	<p style="text-align: right;">Page 89</p> <p>1 cancer. Just cancer in general, many 2 areas, but not ovarian cancer. 3 Q. Have you ever designed a 4 study or helped design a study where there 5 was a focus of trying to determine whether 6 or not a particular risk factor or 7 combination of risk factors were -- are 8 responsible for ovarian cancer? 9 A. Again, I don't recall any 10 studies I have been involved in related to 11 ovarian cancer, so, therefore, the answer 12 to your question would be no. 13 Q. Do you have any articles 14 which in any way bear on any issue relating 15 to talc? 16 A. I'm pretty sure I don't have 17 anything on talc. 18 Q. Prior to this case about a 19 month ago, had you ever read literature 20 relating to talc and ovarian cancer? 21 A. I don't recall reading that. 22 Q. You don't recall reading any? 23 A. Or seeing anything, yeah, no, 24 I don't.</p>

<p style="text-align: right;">Page 90</p> <p>1 Q. So the first time you ever 2 saw any article relating to talc and 3 ovarian cancer was on the 20th of May 2024 4 when the lawyers contacted you in this 5 case? 6 MS. LEHMAN: Object to form. 7 THE WITNESS: So I can't be 8 100 percent sure. I don't know if 9 I saw any news articles on it, 10 sometimes when I'm reading a 11 newspaper, but specifically an 12 academic article on the specifics 13 of talc use related to ovarian 14 cancer, I think the answer is no. 15 BY MR. TISI: 16 Q. Okay. And so just to be 17 100 percent clear so we have a clear answer 18 to this question, before May 20, 2024, you 19 have never read an academic article 20 relating to the relationship between 21 ovarian cancer and talcum powder, true? 22 A. I don't recall reading any 23 such paper at any time. 24 Q. Okay. Prior to this case,</p>	<p style="text-align: right;">Page 92</p> <p>1 issues or do you not know? 2 A. Well, I know from what I've 3 seen in relation to this report that 4 there's also uterine cancer and breast 5 cancer was considered for the Sister Study. 6 I believe the question there was more -- 7 the questionnaires have been more extensive 8 than just looking at talc use, but I 9 wouldn't say that I'm knowledgeable on 10 everything that has come out. 11 Q. Yeah. I mean, just to be 12 clear, you are not familiar -- other than 13 the talc and ovarian cancer papers 14 identified in your report, you have not 15 sought to familiarize yourself with the 16 papers and body of literature that have 17 come out of the Sister Study, true? 18 A. I mean, I sought out papers 19 related to the Sister Study, because 20 they're related to O'Brien (2024) and my -- 21 Q. Right. 22 A. And I was to independently 23 review that. So to the extent that they 24 were related to O'Brien (2024) is what I</p>
<p style="text-align: right;">Page 91</p> <p>1 have you read any literature coming out of 2 the Sister cohort study? 3 A. I don't believe so. 4 Q. Okay. Do you understand that 5 in terms of cohorts and the study of cancer 6 that the Sister Study is an important 7 study? 8 MS. LEHMAN: Object to form. 9 BY MR. TISI: 10 Q. Well, let me rephrase the 11 question. Do you understand that amongst 12 people who actually study cancer risk 13 factors that the Sister Study cohort is a 14 particularly important cohort? 15 MS. LEHMAN: Object to form. 16 THE WITNESS: I don't know 17 what defines whether something is 18 particularly important versus not 19 particularly important, but there 20 are clearly multiple papers about 21 the Sister Study. 22 BY MR. TISI: 23 Q. Right. And not just on talc 24 and ovarian cancer, it's on various other</p>	<p style="text-align: right;">Page 93</p> <p>1 was seeking out. 2 Q. Doctor, this isn't a trick 3 question. I'm asking you other than the 4 papers that are identified in your report, 5 have you sought to familiarize yourself 6 generally with the Sister Study and the 7 research that has come out of it? 8 MS. LEHMAN: Objection. 9 THE WITNESS: I think the 10 materials cited in my report that 11 that's my -- that was a good faith 12 attempt to representing everything 13 I reviewed. I may have gone to the 14 website for the Sister Study, but I 15 don't recall for sure. 16 BY MR. TISI: 17 Q. Have you ever written on 18 imputation, either single or multiple, in a 19 methods paper? In other words, not as part 20 of a methods of a study, but in terms of 21 talking about that imputation as a method 22 for dealing with missingness? 23 A. Yes. 24 Q. Okay. Could you identify</p>

<p style="text-align: right;">Page 94</p> <p>1 where you actually talk about multiple 2 imputation or single imputation as a method 3 for dealing with missingness? 4 A. So it's in my papers related 5 to the Bayesian reconstruction of magnetic 6 resonance -- 7 THE STENOGRAPHER: Wait a 8 minute, the what reconstruction? 9 THE WITNESS: Bayesian, 10 B-A-Y-E-S-I-A-N. 11 BY MR. TISI: 12 Q. And maybe I wasn't clear 13 about my question. My question was not 14 whether or not you discussed it in the 15 context of a paper in which you were 16 looking at something else -- 17 A. No, it's developing missing 18 data, missing data approach. 19 Q. Okay. 20 A. It's developing a method. 21 It's not -- I'm just not implementing a 22 method. 23 Q. And can you tell me which of 24 your articles in your CV that was? And I</p>	<p style="text-align: right;">Page 96</p> <p>1 The last one was about methods and now 2 you're asking just about whether I address 3 any of the issues related to -- 4 Q. No, no, what I'm asking, 5 let's stay focused on imputation for 6 dealing with missingness. Okay. You know, 7 I looked at -- I read your report, I looked 8 at your -- the things that you've cited, 9 your footnotes, and I don't see any of your 10 own literature used to support any of the 11 general propositions about, for example, 12 missing imputation by chain equations or 13 MICE. Or missing not at random or missing 14 completely at random or missing at random, 15 MCAR, I've not seen any of your own 16 research cited in support of your opinions, 17 you've cited other people, but I have not 18 seen your own. Have you had any papers 19 which deal directly with the issues of 20 imputation that you spend the majority of 21 your report dealing with? 22 A. Again, there are papers that 23 have something related to imputation in 24 them. I didn't choose them as -- they're</p>
<p style="text-align: right;">Page 95</p> <p>1 don't want to take forever to do it, but if 2 you can identify which one or ones, that 3 would be helpful. 4 A. So this would be -- I'm going 5 back a ways. So publication 32 and I think 6 publication 29. So these used the idea of 7 Bayesian methods for imputing data. So 8 you're imputing data to higher resolution 9 of the image. 10 Q. Okay. So the reason I'm 11 asking, Doctor, and I'm not playing hide 12 and seek with you here on this, you don't 13 cite any of your published literature in 14 support of the opinions you give about the 15 appropriateness of the imputation 16 methodology used by these authors. Have 17 you ever addressed in any of your published 18 work any of the issues that you are opining 19 on in this case? 20 A. I mean, I definitely have 21 addressed questions about imputation in 22 publications. I would struggle to pinpoint 23 which ones, but this -- you're now asking a 24 completely different question, I believe.</p>	<p style="text-align: right;">Page 97</p> <p>1 not the most appropriate references to cite 2 for supporting my opinions. 3 Q. That's what I'm trying to get 4 at here is, for the purposes of the 5 opinions you're offering in this case about 6 imputation, you have not written 7 independently in the academic literature 8 about those methods specifically? 9 MS. LEHMAN: Object to form. 10 THE WITNESS: I think 11 specifically I have written about 12 those methods, to what extent is 13 another question. And I would have 14 spend a lot of time going through 15 my papers to figure that out. 16 BY MR. TISI: 17 Q. But none pop in your mind 18 right now? 19 MS. LEHMAN: Object to form. 20 THE WITNESS: I mean, I know 21 there are papers in there that 22 consider missing data. I mean, 23 that's just -- and these are 24 statistical methods, some of them</p>

<p style="text-align: right;">Page 98</p> <p>1 have been around for a long, long</p> <p>2 time and bias, as an expert</p> <p>3 biostatistician, I understand those</p> <p>4 methods and when they are</p> <p>5 appropriate to be used in different</p> <p>6 problems.</p> <p>7 BY MR. TISI:</p> <p>8 Q. I'm not suggesting you don't</p> <p>9 understand them, not at this point. My</p> <p>10 question is have you ever written on them</p> <p>11 generally in a methods paper?</p> <p>12 A. Again --</p> <p>13 Q. I don't see any -- I don't</p> <p>14 see any -- I don't see any -- the reason</p> <p>15 why I'm saying that, Doctor, is I don't see</p> <p>16 you citing any of your own academic</p> <p>17 research in support of your opinions. And</p> <p>18 I would have assumed that if you had</p> <p>19 written on the topic, you would have cited</p> <p>20 your own research and you didn't. So can</p> <p>21 you explain that?</p> <p>22 MS. LEHMAN: Objection. Asked</p> <p>23 and answered.</p> <p>24 THE WITNESS: Well, I would</p>	<p style="text-align: right;">Page 100</p> <p>1 Q. It's throughout your report.</p> <p>2 So let me ask you this opinion. Is it your</p> <p>3 opinion that imputation, multiple</p> <p>4 imputation -- let me rephrase it another</p> <p>5 way.</p> <p>6 Is it multiple imputation a</p> <p>7 recognized statistical method to deal with</p> <p>8 missing data in an epidemiologic study?</p> <p>9 A. Multiple imputation is a</p> <p>10 recognized approach to dealing with missing</p> <p>11 data, but it depends on the missing data</p> <p>12 itself to what extent it's appropriate to</p> <p>13 use it.</p> <p>14 Q. Understood. And we're going</p> <p>15 to talk about that, but if anyone were to</p> <p>16 read your report and say, yeah, that</p> <p>17 multiple imputation is like voodoo where</p> <p>18 people are just using fancy terms to guess</p> <p>19 at data, that's not true, is it?</p> <p>20 MS. LEHMAN: Object to form.</p> <p>21 THE WITNESS: I would say in</p> <p>22 general, multiple imputation when</p> <p>23 applied properly, no, it's not</p> <p>24 voodoo, but, however, I think how</p>
<p style="text-align: right;">Page 99</p> <p>1 not make that assumption of</p> <p>2 somebody that just because they've</p> <p>3 written on a topic that they're</p> <p>4 going to prioritize writing</p> <p>5 their -- referencing their paper.</p> <p>6 I mean, maybe people do that, I</p> <p>7 don't know, but I don't think of it</p> <p>8 as being a good academic approach.</p> <p>9 As an academic, I want to cite the</p> <p>10 most relevant literature to what it</p> <p>11 is I'm trying to explain.</p> <p>12 BY MR. TISI:</p> <p>13 Q. And, for example, one of</p> <p>14 the -- well, we'll talk about that later,</p> <p>15 never mind.</p> <p>16 You've called imputation</p> <p>17 throughout this report a guess. It's not a</p> <p>18 guess, is it?</p> <p>19 A. I would like you to point me</p> <p>20 to where I refer to imputation as a</p> <p>21 guess --</p> <p>22 Q. Let them --</p> <p>23 A. -- it depends on what I</p> <p>24 stated.</p>	<p style="text-align: right;">Page 101</p> <p>1 it's applied here, if you want to</p> <p>2 use a pejorative term like you did,</p> <p>3 you might say it is kind of voodoo,</p> <p>4 because it's a level of making</p> <p>5 things up here, yeah.</p> <p>6 BY MR. TISI:</p> <p>7 Q. But, generally speaking, and</p> <p>8 I'm going to move to strike the</p> <p>9 nonresponsive part of your answer, because</p> <p>10 we're going to talk about what the authors</p> <p>11 did. If anyone were to walk in court and</p> <p>12 say that multiple imputation is not a</p> <p>13 recognized statistical method for dealing</p> <p>14 with statistical data, they would be wrong,</p> <p>15 true?</p> <p>16 MS. LEHMAN: Object to form.</p> <p>17 Asked and answered.</p> <p>18 THE WITNESS: Multiple</p> <p>19 imputation is one recognized</p> <p>20 technique for approaching what is</p> <p>21 the problem of having missing data.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Okay. And it is recognized</p> <p>24 in the biostatistic and epidemiologic</p>

<p style="text-align: right;">Page 102</p> <p>1 community as a way not to guess at data, 2 correct? 3 MS. LEHMAN: Object to form. 4 BY MR. TISI: 5 Q. It's a method that -- 6 A. That is not -- that is not 7 correct. 8 Q. Okay. Let me rephrase the 9 question. It's a method for using existing 10 data to predict what the answer would have 11 been had the question been answered, true? 12 A. No. 13 Q. Okay. Tell me what it does. 14 A. What it does is the idea is 15 you have data, the dataset is incomplete in 16 some way, and you then have to make a 17 decision to make a trade-off between is it 18 worth trying to do some kind of imputation 19 with the data, but at the same time, you 20 want to guard that you're not doing more 21 harm than good when you do the imputation. 22 Q. Right. 23 A. So you were talking specific 24 -- you mentioned imputing something</p>	<p style="text-align: right;">Page 104</p> <p>1 designed a program in health data science 2 that has a large component about missing 3 data. So in that sense, I've written about 4 it, but if you're talking about in academic 5 peer-reviewed publications, I haven't 6 provided a commentary on that. 7 Q. Okay. Have you -- are you 8 familiar with any literature that would 9 support your position that multiple 10 imputation would not be used for the 11 primary predictor? 12 A. I don't recall any specific 13 document offhand. This would just be sort 14 of, like, conventional sort of 15 biostatistical thinking, based on my 16 experience and knowledge as a 17 biostatistician. I'm sure it's discussed 18 in textbooks, but I can't point you to a 19 specific textbook. 20 Q. And you can't think of a 21 textbook or an article which talks about 22 when the boundary line of when you use 23 multiple imputation with respect to the 24 variables that you're studying, true?</p>
<p style="text-align: right;">Page 103</p> <p>1 specific I think related to, like, the 2 primary predictor of exposure or something. 3 But here where multiple imputation can help 4 in particular is when you have variables 5 that are not providing much information 6 directly to the primary outcome, but you 7 don't want to throw the whole set of 8 information away from a subject, and so 9 you, you kind of, it becomes a trade-off 10 where you say I would risk the imputation 11 of that data point in order to get the 12 extra bit of data -- 13 Q. But you don't -- 14 A. -- of everything on that 15 individual. But that's usually the 16 thinking on multiple imputation, not on 17 trying to impute your most important 18 predictors when there's a lot of missing 19 data. 20 Q. So is there any -- well, 21 first of all, have you ever written on how 22 to deal with missingness in epidemiologic 23 studies? 24 A. To the extent where -- I have</p>	<p style="text-align: right;">Page 105</p> <p>1 A. Oh, no, I can. I mean, 2 Rubin's book on multiple imputation 3 certainly talks about when, like, things 4 with respect to being missing completely, 5 at random, missing at random, missing not 6 at random, other textbooks in the field 7 surely talk about that too. 8 Q. Right. But that book, using 9 that as an example, doesn't say that you 10 only -- you do not use multiple imputation 11 with respect to the primary outcome that 12 you're studying, true? 13 A. I would just simply say 14 that's a qualified true, but there is no 15 sort of black and white boundary on when 16 you are overdoing these things versus not 17 overdoing these things. There is, like I 18 said originally, a trade-off between what 19 you want to impute and what the benefits 20 might be. 21 A common practice though is 22 to rerun analyses where whenever you are 23 kind of even nervous about the imputation 24 influencing your results, that you will run</p>

<p style="text-align: right;">Page 106</p> <p>1 with and without imputation as a 2 sensitivity analysis and check that your 3 results have not been greatly affected by 4 your imputation approach. That's a common 5 practice and -- 6 Q. Let me just give -- I'm kind 7 of jumping ahead here, but this let me ask 8 you this. The authors were very clear up 9 front as to why they were using the 10 imputation methods to try to predict when 11 people were actually -- women were actually 12 using talc when that information was 13 missing in the follow-up questionnaire, 14 true? 15 I'm not asking you whether 16 it was right or wrong, I'm asking you, they 17 laid it out there for the whole world to 18 see, correct? 19 A. They basically said that they 20 were going to impute exposure status, yes. 21 Q. Correct. And that went 22 through peer review, true? 23 A. I mean, it did. I'm amazed 24 it did. I can't understand how -- they</p>	<p style="text-align: right;">Page 108</p> <p>1 MS. LEHMAN: Objection. Asked 2 and answered. 3 THE WITNESS: Those methods 4 applied in certain situations have 5 been criticized many times over. 6 BY MR. TISI: 7 Q. Okay. Well, you tell me who, 8 tell me who has criticized O'Brien (2024)? 9 A. I didn't say anybody 10 criticized O'Brien (2024). I said that 11 those methods when used inappropriately 12 have been criticized many times over. 13 Q. So listen to my question, if 14 you don't mind, okay? This paper was 15 published in the peer-reviewed journal on 16 May 15 by NIH scientists; is that true? 17 MS. LEHMAN: Object to form. 18 THE WITNESS: My understanding 19 is that the authors of the paper 20 work at the NIH. My understanding 21 is that this paper was published 22 and so -- and that it's a 23 peer-reviewed journal, so. 24</p>
<p style="text-align: right;">Page 107</p> <p>1 must have not had biostatistical review, 2 because that was amazing that that got 3 through without -- 4 Q. Okay. And nobody has ever -- 5 and we're going to talk about this, but to 6 your knowledge, not a single scientist 7 outside of this litigation has criticized 8 in any way the imputation used by these 9 scientists, true? 10 MS. LEHMAN: Object to form. 11 THE WITNESS: No, that's not 12 true. I mean, people have 13 criticized imputation approaches 14 being applied inappropriately 15 often. 16 BY MR. TISI: 17 Q. Let me rephrase the question 18 and I apologize if I was unclear. I said 19 other than experts in this litigation who 20 have been hired by Johnson & Johnson, and 21 paid a lot of money, not a single scientist 22 outside of this litigation has criticized 23 the O'Brien (2024) imputation methods, have 24 they, to your knowledge?</p>	<p style="text-align: right;">Page 109</p> <p>1 BY MR. TISI: 2 Q. So the answer to my 3 question -- 4 A. Peer reviewed is not a 5 perfect process, so -- 6 Q. The answer to my question 7 was, yes, it was published by NIH 8 scientists on May 15 in a peer-reviewed 9 journal, true? 10 MS. LEHMAN: Objection. Asked 11 and answered. 12 THE WITNESS: Yes, it was 13 published in a peer-reviewed 14 journal. 15 BY MR. TISI: 16 Q. Okay. And from May 15, it is 17 now mid July, okay, have you seen any 18 public criticisms in the academic 19 literature other than by people hired by 20 Johnson & Johnson and made a lot of money? 21 MS. LEHMAN: Object to form. 22 THE WITNESS: I have not, but 23 I would be absolutely stunned if 24 anything made it through the</p>

<p style="text-align: right;">Page 110</p> <p>1 peer-review process so quickly 2 between the paper being published 3 and now. Academic literature 4 doesn't tend to move that fast. 5 BY MR. TISI: 6 Q. Okay. But so the answer to 7 the question would be no, you're not aware 8 of anybody outside of being hired by 9 Johnson & Johnson who has criticized this 10 paper in a conference, at a meeting, in a 11 conference call, in a letter to the editor, 12 in an editorial, in a paper, anywhere other 13 than Johnson & Johnson's paid experts, 14 true? 15 MS. LEHMAN: Object to form. 16 THE WITNESS: I'm just -- I 17 don't -- I have not seen anything 18 myself. I just independently 19 reviewed the paper and my opinions 20 are that it's flawed and 21 unreliable. 22 BY MR. TISI: 23 Q. Okay. Now, let's talk about 24 those NIH authors in which you said you are</p>	<p style="text-align: right;">Page 112</p> <p>1 have been written regarding talc and 2 ovarian cancer from the Sister Study 3 cohort, correct? 4 A. Yes. 5 Q. And you refer to several of 6 them, one would be Gonzalez 2016, which 7 would have been about six and a half years 8 after the study was commenced and that's 9 Exhibit No. 18 in your book. 10 MS. LEHMAN: Object to form. 11 THE WITNESS: I think it's a 12 little bit longer than that, right, 13 2016 from 2003, that would be about 14 13 years later. 15 ----- 16 (Gonzalez Study marked 17 Kornak Exhibit 18 for 18 identification.) 19 ----- 20 BY MR. TISI: 21 Q. Right. But they used, they 22 used data that was about 6.6 years in 23 follow-up, do you remember? 24 MS. LEHMAN: Object to form.</p>
<p style="text-align: right;">Page 111</p> <p>1 not criticizing them in particular, true? 2 A. I am not criticizing them 3 personally in any way. 4 Q. Well, professionally, are you 5 criticizing them? 6 MS. LEHMAN: Object to form. 7 THE WITNESS: Well, I'm 8 criticizing them professionally in 9 terms of this work that -- in terms 10 of the paper that they wrote, yes. 11 BY MR. TISI: 12 Q. All right. So let's go, if 13 you don't mind going to Exhibit No. 8, 14 which is O'Brien (2024). 15 A. Yeah, I'm there. 16 Q. Now, you know from reading 17 the paper that this is a study where almost 18 over 50,000 people, we talked about this, 19 over 50,000 women were enrolled and the 20 study is about 15 years old, correct? 21 A. It seems like the study 22 started collecting data in 2003, so I would 23 say that's, like, 22 years old. 24 Q. Okay. And several papers</p>	<p style="text-align: right;">Page 113</p> <p>1 THE WITNESS: Well, they had a 2 median follow-up of 6.6 years. 3 BY MR. TISI: 4 Q. Okay. And you also -- 5 A. Something like that. 6 Q. -- looked at a pooled 7 study by -- and O'Brien herself was part of 8 the Gonzalez study in 2016, correct? 9 A. Yes, she's the second author 10 on that paper. 11 Q. And there was also a pooled 12 study of cohorts, O'Brien (2020), which is 13 in your book as Exhibit 25? 14 A. Yes, that's correct. 15 ----- 16 (O'Brien (2020) Study marked 17 Kornak Exhibit 25 for 18 identification.) 19 ----- 20 BY MR. TISI: 21 Q. All right. O'Brien is also 22 on that study, correct? 23 A. Yes, she's the first author 24 on that one.</p>

<p style="text-align: right;">Page 114</p> <p>1 Q. As is Dale Sandler. Do you 2 see that? 3 A. Yes. 4 Q. Okay. Nicolas Wentzensen? 5 A. Yes. 6 Q. And Holly Harris. Do you see 7 her name? 8 A. Yes. 9 Q. Clarice Weinberg? 10 A. Yes. 11 Q. She's a biostatistician, 12 correct? 13 A. I don't know. 14 Q. Okay. Now, there's also a 15 study on -- that touches on talc recall 16 bias, which is O'Brien (2023), correct? 17 A. Yes. 18 Q. And that's Exhibit No. 16. 19 A. Yes. 20 ----- 21 (O'Brien (2023) marked 22 Kornak Exhibit 16 for 23 identification.) 24 -----</p>	<p style="text-align: right;">Page 116</p> <p>1 Exhibit 22 for identification.) 2 ----- 3 BY MR. TISI: 4 Q. Okay. And Dale Sandler is 5 part of that study as well, correct? 6 A. Yeah, I see his name. 7 Q. It's actually a she. 8 A. Sorry, she. My bad. 9 Q. That's okay. And, of course, 10 there's O'Brien (2024), Exhibit No. 8 where 11 these same authors appear again, true? 12 A. That's true. 13 Q. Okay. And in addition to 14 this, okay, O'Brien has written other 15 things on the talc ovarian cancer 16 association, for example, response to 17 letter to the editors that we just talked 18 about, Exhibit No. 25 in your book, 19 correct? 20 A. The responses you said are 21 Exhibit 25 or is that a different -- 22 Q. No, Exhibit No. 25. 23 A. I received Exhibit No. 25 as 24 a paper.</p>
<p style="text-align: right;">Page 115</p> <p>1 BY MR. TISI: 2 Q. Okay. It's entitled 3 "Douching and genital talc use: Patterns 4 of use and reliability of self-reported 5 exposure," correct? 6 A. Correct. 7 Q. And the authors on that are, 8 again, Dr. O'Brien, Dr. Wentzensen, and 9 Dr. Sandler, correct? 10 A. Yes. 11 Q. Okay. These are the same 12 authors who appear over and over in these 13 studies publishing the peer-reviewed 14 literature coming out of the Sister Study, 15 correct? 16 A. Yes. 17 Q. Okay. The next one is a 18 study of personal care product mixtures in 19 different cancers by Chang, Exhibit 22, in 20 your book. If you could bring up 21 Exhibit 22, Jeff. 22 A. I have it open here. 23 ----- 24 (Chang Study marked Kornak</p>	<p style="text-align: right;">Page 117</p> <p>1 Q. I'm sorry. I'm sorry, 2 Exhibit No. 26. And she wrote a response 3 to letters that were written to her about 4 O'Brien (2020), correct it would be on the 5 second page of that document. Third page, 6 I'm sorry. 7 A. Yes. 8 ----- 9 (O'Brien Response to Letter 10 to the Editor marked Kornak 11 Exhibit 26 for identification.) 12 ----- 13 BY MR. TISI: 14 Q. Okay. So it's fair to say 15 that these authors from the NIH have 16 published a lot of literature of talc and 17 ovarian cancer coming out of the Sister 18 Study, true? 19 MS. LEHMAN: Object to form. 20 THE WITNESS: They have 21 published multiple papers that use 22 the Sister Study data. 23 BY MR. TISI: 24 Q. And you had not seen any of</p>

<p style="text-align: right;">Page 118</p> <p>1 them before May 20, 2024, true?</p> <p>2 A. I believe that is true.</p> <p>3 Q. Okay.</p> <p>4 A. But, anyway -- sorry.</p> <p>5 Q. Would you expect these</p> <p>6 people, these NIH scientists, who have been</p> <p>7 publishing from the Sister Study on talc</p> <p>8 and ovarian cancer for going on 20 years to</p> <p>9 know and understand their cohort and their</p> <p>10 data?</p> <p>11 MS. LEHMAN: Object to form.</p> <p>12 THE WITNESS: Well, I don't</p> <p>13 know that they have been publishing</p> <p>14 for 20 years. I know that 2016,</p> <p>15 since then for sure, they have been</p> <p>16 publishing on this.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Okay.</p> <p>19 A. So but what was the question</p> <p>20 again?</p> <p>21 Q. Well, let me ask you this.</p> <p>22 Would you expect them to know and</p> <p>23 understand the data, they have been working</p> <p>24 with this data for a long time, true?</p>	<p style="text-align: right;">Page 120</p> <p>1 and I assume they are qualified</p> <p>2 researchers in what they're working</p> <p>3 on.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Well, do you have any</p> <p>6 evidence, as we sit here today, Dr. Kornak,</p> <p>7 that any of these NIH scientists who</p> <p>8 drafted or were responsible for drafting</p> <p>9 O'Brien (2024) or any of the prior studies</p> <p>10 have been -- have received a penny from any</p> <p>11 side in this talc litigation?</p> <p>12 A. I don't know if -- whether</p> <p>13 they have or they haven't. I don't know.</p> <p>14 Q. Well, that's actually a</p> <p>15 different question. Do you have any</p> <p>16 evidence, as you sit here today, that they</p> <p>17 have received --</p> <p>18 A. No.</p> <p>19 Q. -- even a penny in money from</p> <p>20 lawyers involved in talc litigation?</p> <p>21 MS. LEHMAN: Object to form.</p> <p>22 Asked and answered.</p> <p>23 THE WITNESS: I don't have any</p> <p>24 such evidence.</p>
<p style="text-align: right;">Page 119</p> <p>1 A. They have been working with</p> <p>2 the data at baseline for a while.</p> <p>3 Q. And they have been crafting</p> <p>4 the follow-up questionnaires, true?</p> <p>5 A. I don't know if they were</p> <p>6 involved in crafting the follow-up</p> <p>7 questionnaire. I know they're involved in</p> <p>8 the Sister Study, but I don't know to what</p> <p>9 extent.</p> <p>10 Q. But you don't know the roles,</p> <p>11 the respective roles that they had with the</p> <p>12 Sister Study, true?</p> <p>13 A. I don't know their roles</p> <p>14 completely.</p> <p>15 Q. Okay. Have you looked at</p> <p>16 their qualifications on -- from the NIH</p> <p>17 website in order to understand their roles</p> <p>18 not only in looking at the Sister Study</p> <p>19 cohort, but in looking at cohort data in</p> <p>20 multiple cohorts?</p> <p>21 MS. LEHMAN: Object to form.</p> <p>22 THE WITNESS: I have not</p> <p>23 looked at their qualifications. I</p> <p>24 see that they're either MDs or PhDs</p>	<p style="text-align: right;">Page 121</p> <p>1 BY MR. TISI:</p> <p>2 Q. Okay. Do you have any</p> <p>3 information that any of these NIH</p> <p>4 scientists who published O'Brien (2024)</p> <p>5 have been retained as a litigation</p> <p>6 consultant in any fashion?</p> <p>7 A. No.</p> <p>8 Q. Okay. Now, you have been a</p> <p>9 consultant and expert for this litigation,</p> <p>10 do you have any evidence that any of these</p> <p>11 NIH scientists have participated in any</p> <p>12 legal matter, talc or otherwise, at any</p> <p>13 time in their professional careers?</p> <p>14 MS. LEHMAN: Object to form to</p> <p>15 counsel testifying.</p> <p>16 THE WITNESS: I don't have any</p> <p>17 evidence on what -- whether they've</p> <p>18 been involved in legal proceedings</p> <p>19 in their careers.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Well, you don't have any</p> <p>22 evidence that they have, true?</p> <p>23 A. I don't have any evidence,</p> <p>24 no.</p>

<p style="text-align: right;">Page 122</p> <p>1 Q. Do you have any reason to</p> <p>2 doubt their independence when drafting</p> <p>3 studies that they send in for peer review</p> <p>4 on the Sister Study?</p> <p>5 A. I don't have any such</p> <p>6 evidence and, you know, I don't know these</p> <p>7 people, so I'm not --</p> <p>8 Q. If somebody were to walk into</p> <p>9 court tomorrow and say these experts had in</p> <p>10 their mind to publish a paper where the</p> <p>11 outcome was that talc was associated with</p> <p>12 ovarian cancer as -- before they even</p> <p>13 started the study, that would be -- there</p> <p>14 would be no evidence for that, right?</p> <p>15 MS. LEHMAN: Object to form.</p> <p>16 THE WITNESS: Well, I would</p> <p>17 say, no, that -- I mean, this --</p> <p>18 there is kind of evidence to that</p> <p>19 in a way. I mean, you're kind of</p> <p>20 getting -- putting me in a</p> <p>21 hypothetical position about what's</p> <p>22 in the mind --</p> <p>23 BY MR. TISI:</p> <p>24 Q. Well, it's not</p>	<p style="text-align: right;">Page 124</p> <p>1 clearly here in the paper that there are</p> <p>2 problems with what -- they're relying on</p> <p>3 this forward retrospective analysis when</p> <p>4 they have clean prospective data that they</p> <p>5 could be focused on.</p> <p>6 Q. And let's talk about --</p> <p>7 A. And they mentioned, they said</p> <p>8 they relegated that down into the appendix.</p> <p>9 Q. Okay. We're going to talk</p> <p>10 about that. We're going to talk about what</p> <p>11 they did, but I'm going to move to strike</p> <p>12 your answer. Do you have any --</p> <p>13 THE STENOGRAPHER: You froze.</p> <p>14 BY MR. TISI:</p> <p>15 Q. I move to strike your answer</p> <p>16 as nonresponsive. Do you have any evidence</p> <p>17 that you can point to that these -- that</p> <p>18 these NIH scientists who have never been</p> <p>19 paid in litigation, to your knowledge,</p> <p>20 engaged in an analysis with an intent to</p> <p>21 find an association where none exists?</p> <p>22 MS. LEHMAN: Object to form.</p> <p>23 Asked and answered.</p> <p>24 THE WITNESS: Just that,</p>
<p style="text-align: right;">Page 123</p> <p>1 hypothetical --</p> <p>2 MS. LEHMAN: Hold on. Hold</p> <p>3 on. Just let him finish. Let</p> <p>4 Dr. Kornak finish, please.</p> <p>5 BY MR. TISI:</p> <p>6 Q. I'm asking whether you</p> <p>7 have any --</p> <p>8 A. I would like to finish my</p> <p>9 answer --</p> <p>10 Q. Well, I want to --</p> <p>11 A. I really want to finish what</p> <p>12 I was saying before I lose my train of</p> <p>13 thought --</p> <p>14 Q. All right. Finish and I'll</p> <p>15 move to strike.</p> <p>16 A. These authors have produced a</p> <p>17 paper that seems to go in a different</p> <p>18 direction to where they were -- their</p> <p>19 previous papers. They were using flawed</p> <p>20 approaches and so, you know, I don't know</p> <p>21 what their exact reason is for doing this,</p> <p>22 whether they just wanted to get another</p> <p>23 paper out and saying the same thing doesn't</p> <p>24 get you another paper out. But it's</p>	<p style="text-align: right;">Page 125</p> <p>1 again, I don't know their motives,</p> <p>2 but they produced a paper which</p> <p>3 appears to do as much juggling as</p> <p>4 possible to try to find a result</p> <p>5 where none really exists.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Let's go to Exhibit No. 10,</p> <p>8 if we could, in your binder. This is the</p> <p>9 NIH biography of Dale Sandler. She's a</p> <p>10 senior investigator in the epidemiology</p> <p>11 branch, chronic disease, epidemiology group</p> <p>12 at the National Institute of Environmental</p> <p>13 Health Sciences of the NIH.</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 - - - - -</p> <p>17 (Dale Sander, PhD, Bio</p> <p>18 marked Kornak Exhibit 10 for</p> <p>19 identification.)</p> <p>20 - - - - -</p> <p>21 BY MR. TISI:</p> <p>22 Q. Okay. That's a pretty --</p> <p>23 that's a pretty important position, do you</p> <p>24 agree?</p>

<p style="text-align: right;">Page 126</p> <p>1 A. You know, I'm not familiar 2 with NIH internal hierarchy as to what 3 different positions mean, but I have no 4 reason to doubt her credentials. 5 Q. Okay. If you go to page 3, 6 it says "Dale Sandler, heads the Chronic 7 Disease Epidemiology group and has been 8 Chief of the Epidemiology Branch of the 9 Division of Intramural Research at NIEHS 10 since 2003." 11 Do you see that? 12 A. Yes. 13 Q. Is that, if you were to get 14 that as an application to your school, you 15 would consider that to be a pretty 16 impressive credential, true? 17 MS. LEHMAN: Object to form. 18 THE WITNESS: I mean, you 19 know, it seems to be a potentially 20 important position. I don't know 21 the internal workings of, like, the 22 NIH hierarchy, but she has -- 23 BY MR. TISI: 24 Q. It further states that she --</p>	<p style="text-align: right;">Page 128</p> <p>1 good for her that she got an award. 2 Again, I'm not in any way doubting 3 her credentials, but I don't know 4 the specifics of how these awards 5 are made. But, you know, great. 6 BY MR. TISI: 7 Q. If you had gotten her -- if 8 you had gotten an application for her 9 medical -- for your school at UCSF, would 10 you have given it a look? 11 A. If we were hiring and, sure, 12 her CV would be considered along with all 13 CVs that were -- or all applications that 14 were made for a position. But, yes, she 15 would receive consideration and she has, 16 presumably, she has the qualifications for 17 certain positions. 18 Q. Let's look at Katie O'Brien, 19 Exhibit No. 8. By the way, actually, never 20 mind. Do you see -- 21 A. You said Exhibit No. 8. 22 Q. Exhibit No. 9, excuse me. 23 A. Go ahead. 24 - - - - -</p>
<p style="text-align: right;">Page 127</p> <p>1 I'm sorry, go ahead. 2 A. No, I'm just going to give 3 you an example within UCSF, you can have 4 people that head groups and it's really 5 them and a postdoc, so I don't know what 6 this means, but, again, I'm not doubting 7 this person's credentials. 8 Q. Okay. It says that she was a 9 past president of the American College of 10 Epidemiology. 11 Do you see that? 12 A. Yes. 13 Q. Are you a member of the 14 American College of Epidemiology? 15 A. No, I'm not a member. 16 Q. Okay. It says she received 17 the NIH directors award in 2009 for 18 developing the Sister Study. 19 Do you see that? 20 A. Yes. 21 Q. Okay. Is that something that 22 you consider to be an impressive position? 23 MS. LEHMAN: Object to form. 24 THE WITNESS: I think it's</p>	<p style="text-align: right;">Page 129</p> <p>1 (Katie O'Brien, PhD, Bio 2 marked Kornak Exhibit 9 for 3 identification.) 4 - - - - - 5 BY MR. TISI: 6 Q. She's a member of the Chronic 7 Disease Epidemiologist Group. 8 Do you see that? 9 A. Yes. 10 Q. And the next page, page 2, 11 its says "She's a staff scientist in the 12 Epidemiology Branch, where she helps lead 13 the Sister Study, a prospective cohort 14 study designed to identify environmental 15 and genetic risk factors for breast cancer. 16 Within the study, O'Brien's main interests 17 include how environmental and 18 hormone-related exposures are related to 19 breast, ovarian and uterine cancers." 20 Do you see that? 21 A. Yes. 22 Q. Okay. Do you have any reason 23 to doubt Katie O'Brien's credentials? 24 A. She's a PhD and I don't know</p>

<p style="text-align: right;">Page 130</p> <p>1 what her PhD is in, but no, I'm not saying 2 that she's not credentialed. 3 Q. Do you have any reason to 4 believe based upon her biography that she's 5 unqualified to methodologically construct 6 or author a study like O'Brien (2024)? 7 A. I don't see in here that she 8 has basically the biostatistical expertise 9 to deal with the kind of methodological 10 issues that are involved in all of the 11 imputation and correction processes and 12 made up steps in O'Brien (2024). 13 Q. Okay. Let's talk about 14 somebody who may actually do that. Can we 15 go to Exhibit No. 12? This is the 16 biography, the NIH biography of Clarice 17 Weinberg, PhD, Senior Investigator 18 Biostatistics and Computational Biology 19 Branch at NIEHS. 20 Do you see that? 21 A. Yes. 22 ----- 23 (Clarice Weinberg, PhD, bio 24 marked Kornak Exhibit 12 for</p>	<p style="text-align: right;">Page 132</p> <p>1 A. Yes. 2 Q. And she's one of the 3 coauthors on O'Brien (2024), true? 4 A. I don't remember the list of 5 coauthor names, but I think -- 6 Q. Exhibit No. 8, she's right 7 there in the front. 8 A. I'm not doubting you, I just 9 wanted to double-check. Yes, she's there. 10 Q. Okay. 11 A. Yeah. 12 Q. So there is a biostatistician 13 on this paper who is -- you have no reason 14 to doubt their -- who is actually the head 15 of the biostatistics branch for almost 20 16 years at the National Institute of 17 Environmental Health Sciences, correct? 18 A. Yeah. 19 Q. Do you have any reason to 20 believe that she doesn't understand 21 imputation methods or how to correct for 22 recall bias? 23 A. I mean, all I can say is she 24 was a coauthor on there and that she is</p>
<p style="text-align: right;">Page 131</p> <p>1 identification.) 2 ----- 3 BY MR. TISI: 4 Q. And if you go to the second 5 page, it says in her biography, okay, it 6 says she was elected fellow of the American 7 Statistical Association in 1995, awarded 8 both the Janet Norwood Award and Mantel 9 Award in 2005, and was elected to the 10 American Epidemiologic Study in 2007. 11 Do you see that? 12 A. Yes. 13 Q. And do you also see that she 14 is -- it says above that "After serving on 15 the faculty of the Department of 16 Biostatistics in Seattle for two years, she 17 came NIEHS in 1983, where she headed up the 18 Biostatistics Branch since 1997." 19 Do you see that? 20 A. Yes. 21 Q. Okay. So she heads the 22 biostatistics branch at the National 23 Institute of Environmental Health Sciences, 24 correct?</p>	<p style="text-align: right;">Page 133</p> <p>1 greatly credentialed in biostatistics and 2 I'm amazed that if she looked at this 3 closely enough that she let it go through 4 with her name on it with all of those flaws 5 that are in the paper. I certainly would 6 not have done it and I would have asked to 7 be taken off. 8 Q. Let's go to Exhibit No. 11. 9 This is Nicolas Wentzensen, a senior 10 investigator, the Clinical Genetics Branch 11 and National Cancer Institute and he's an 12 MD, PhD, correct? 13 A. Where does it say that? I 14 don't doubt -- oh, yeah, sorry, I see MD, 15 PhD, yes. 16 ----- 17 (Nicolas Wentzensen, MD, 18 PhD, Bio marked Kornak Exhibit 11 19 for identification.) 20 ----- 21 BY MR. TISI: 22 Q. And if you go to page 3, with 23 respect to ovarian cancer specifically, it 24 says "Together with extramural researchers,</p>

<p style="text-align: right;">Page 134</p> <p>1 I established the Ovarian Cancer Cohort 2 Consortium (OC3) to conduct well-powered 3 studies of risk factors and biomarkers for 4 histologic subtypes," correct? 5 A. That is what is stated there, 6 yes. 7 Q. Okay. So do you have any 8 reason to believe that he doesn't 9 understand how to analyze cohort data with 10 respect to ovarian cancer and risk factors? 11 A. Other than the fact that he 12 put his name on this paper when he's 13 clearly using flawed analysis, I can't 14 point to anything else. I don't know the 15 professor and I don't know his history of 16 publications -- 17 Q. Let's look at it -- 18 A. I don't know his 19 biostatistical expertise. 20 Q. Let's look at his biography 21 on the next page, page 4, he received an MD 22 in 2000 and a PhD in 2007. 23 Do you see that? 24 A. Yes.</p>	<p style="text-align: right;">Page 136</p> <p>1 clinical areas and they suddenly do not 2 have the charts to deal with this kind of 3 problem. So, like I said, I don't know Dr. 4 Wentzensen. He does have an MD. He does 5 have a PhD. He has credentials. But I 6 don't see evidence that he has the 7 biostatistical skills to know how to review 8 the paper. 9 Q. Okay. All right. So I'm 10 going to show you Exhibit No. 13, which is 11 a report of the OC3 cohort where Dr. 12 Wentzensen is the last author. 13 Do you see that? 14 A. Yes. 15 ----- 16 (OC3 Cohort Profile marked 17 Kornak Exhibit 13 for 18 identification.) 19 ----- 20 BY MR. TISI: 21 Q. You see Dale Sandler up 22 there? Three lines up. 23 A. It will take me a little 24 while to go through here.</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. He became, if you go down, it 2 says he became a tenure-track investigator 3 in 2009 and was awarded scientific tenure 4 by the NIH and appointed senior 5 investigator in 2013. 6 Do you see that? 7 A. Yes. 8 Q. And it says his "research is 9 focused on clinical epidemiology of 10 gynecological cancers. His research has 11 been highly recognized internationally." 12 Do you see that? 13 A. Yes. 14 Q. Do you have any reason to 15 believe that he doesn't understand how to 16 construct a study that would look at risk 17 factors for ovarian cancer? 18 A. Again, I don't know this 19 person individually what -- he's clearly 20 credentialed in what he knows, but I work 21 with people all the time who are clearly 22 credentialed in what they know and they 23 come to me for biostatistical advice. 24 People who are experts in all kinds of</p>	<p style="text-align: right;">Page 137</p> <p>1 Q. Three lines up, right there, 2 right? 3 A. Yes, I see Dale Sandler. 4 Q. Okay. Katie O'Brien is 5 there? 6 A. I'll just watch your cursor, 7 rather than -- where is Katie O'Brien? Oh, 8 yeah. Yup. 9 Q. And this is not just a Sister 10 Study, this is an Ovarian Cancer Cohort 11 Consortium published in the International 12 Journal of Epidemiology. 13 Do you see that? 14 A. Yes. 15 Q. And if you go down, it says 16 "The Ovarian Cancer Cohort Consortium was 17 established to facilitate prospective 18 studies of ovarian cancer risk factors, 19 biomarkers, risk prediction and outcomes 20 while accounting for ovarian cancer 21 subtypes. 22 "The consortium currently 23 includes 1.3 million women, among which 24 7,314 incidence of epithelial ovarian</p>

<p style="text-align: right;">Page 138</p> <p>1 cancer have been identified." 2 Do you see that? 3 A. Yes. 4 Q. Okay. And Dr. Wentzensen and 5 Dr. O'Brien, and Dr. Sandler are all part 6 of that consortium, correct? 7 A. They're all coauthors on this 8 paper, I don't know -- 9 Q. Do you think that they would 10 be part of this consortium of 1.3 million 11 women if they didn't have any idea how to 12 analyze cohort data? 13 MS. LEHMAN: Object to form. 14 THE WITNESS: Well, first -- 15 sorry, I'm going to, like, the 16 first part of your question, I 17 don't know that they are part of 18 this consortium. I see they're 19 coauthors on this paper. They may 20 well be and I have no reason to 21 doubt that they are, but I don't 22 know that for sure. There are many 23 sort of consortium papers where 24 other people are added as coauthors</p>	<p style="text-align: right;">Page 140</p> <p>1 have been involved in cohort 2 studies of breast cancer, which I 3 believe count as gynecological 4 cancers. 5 BY MR. TISI: 6 Q. You weren't even involved -- 7 you weren't even aware that there was an 8 Ovarian Cancer Cohort Consortium until I 9 just showed you this paper five minutes 10 ago, true? 11 MS. LEHMAN: Object to form. 12 THE WITNESS: I don't know 13 whether I saw this in any of the 14 documents that I reviewed. There 15 was a lot of materials that I've 16 reviewed. But I certainly wouldn't 17 say I'm highly familiar with the 18 Ovarian Cancer Cohort Consortium. 19 BY MR. TISI: 20 Q. Will you go to exhibit -- 21 A. There was your other part of 22 the question was about whether they're able 23 to analyze cohort studies, I believe, and 24 in that respect, the fact that what the</p>
<p style="text-align: right;">Page 139</p> <p>1 that are not part of the 2 consortium, so -- 3 BY MR. TISI: 4 Q. Well, you saw that Dr. 5 Wentzensen, when I pulled up his biography, 6 he actually organized this, correct? 7 A. I mean, yeah, I accept that 8 Dr. Wentzensen is part of the consortium. 9 I just don't know about the others. 10 Q. Okay. 11 A. And I have no reason to doubt 12 it, please don't get me wrong. 13 Q. Well, you're not part of 14 anything like this, are you? You're not 15 part of -- you have never studied or been 16 involved with any cohort data with respect 17 to any gynecologic cancer, have you? 18 MS. LEHMAN: Object to form. 19 THE WITNESS: Strictly 20 speaking, I think -- I mean, I 21 don't think that's the -- the point 22 is I'm a biostatistician and my 23 math is applicable across a wide 24 range of areas, but I certainly</p>	<p style="text-align: right;">Page 141</p> <p>1 authors did in O'Brien (2024) does not bode 2 well for saying that they do a good job of 3 analyzing cohort studies, because the -- 4 and I'm really quite amazed, to be honest 5 here, you know, this is talking about 6 facilitating prospective studies and yet 7 O'Brien is all about retrospective 8 analysis -- 9 Q. All right. Well, we're going 10 to talk about that in a minute, but let me 11 just ask you this question now. In cohort 12 studies, it is not unusual at all for 13 follow-up questionnaires to be issued when 14 a research question comes up, true? 15 A. And I'm trying to think of 16 specific analysis situations. I mean, 17 usually in cohort studies, if you want to 18 look at things longitudinally, you decide 19 that before you start the cohort study and 20 you have a prespecified plan of what -- 21 when you will be collecting data, what will 22 be in that data. If you're going to modify 23 that in any way, that gets -- goes into the 24 protocol in some way, but -- so I think</p>

<p style="text-align: right;">Page 142</p> <p>1 it's kind of unusual to just kind of 2 like -- 3 Q. Really? 4 A. -- decide you're going to do 5 another survey or something, yeah. 6 Q. Okay. So let me ask you this 7 question. Are you aware that there are 8 other cohort studies which have looked at 9 the question of talc and ovarian cancer 10 including the Women's Health Initiative, 11 the Nurses' Study? 12 A. Yes, I mean they're in 13 O'Brien (2020) as part of their combined 14 analysis. 15 Q. Do you know that the talc use 16 wasn't part of the original enrollment 17 questionnaire, but was only asked in a 18 subsequent questionnaire during the course 19 of those cohorts. 20 Do you know that? 21 A. I wouldn't say -- I may have 22 seen it when I was going through the 23 O'Brien (2020) paper, if it's there. I 24 don't recall it specifically. But if</p>	<p style="text-align: right;">Page 144</p> <p>1 Initiative cohorts, correct? 2 A. I've seen that those were in 3 O'Brien (2020), I believe. 4 Q. And you did not know that the 5 question about talc use wasn't asked at the 6 enrollment, you didn't know that, correct? 7 A. I don't recall that, no. 8 Q. Okay. 9 A. Yeah. 10 Q. If I am correct, and I know 11 that I am, that those questions weren't 12 asked until after the study was initiated, 13 many years after the study was initiated, 14 would that call into question the 15 reliability of those studies, in your 16 opinion? 17 MS. LEHMAN: Object to form. 18 THE WITNESS: It would give me 19 concern about inference from that 20 study incorporating additional 21 sources of bias, such as recall 22 bias. I would look at specifically 23 the design and the timeline to 24 follow that, that wasn't the focus</p>
<p style="text-align: right;">Page 143</p> <p>1 that's the case, then that weakens my 2 perspective of that study. 3 Q. Okay. So if it is true, 4 okay, that cohort studies upon which J&J 5 has relied on in this litigation asked 6 questions about talc use in a subsequent 7 questionnaire, those turn those studies 8 into case-control studies, retrospective 9 case-control studies; is that your opinion? 10 MS. LEHMAN: Objection. 11 THE WITNESS: I mean that -- 12 BY MR. TISI: 13 Q. Let me rephrase the 14 question -- 15 A. -- was a convoluted question 16 and I couldn't follow it. 17 Q. Let me rephrase that 18 question. If those studies, 19 hypothetically, use -- 20 A. Are we talking about any 21 other specific studies or something -- 22 Q. Yeah, let's talk specific. 23 You said you had seen reference to the 24 Nurses' Health Study and the Women's Health</p>	<p style="text-align: right;">Page 145</p> <p>1 of my -- I'm not opining on that 2 study per se. 3 BY MR. TISI: 4 Q. The lawyers didn't ask you to 5 do that, did they? 6 MS. LEHMAN: Object to form. 7 THE WITNESS: No, I mean, I 8 was asked to give an independent 9 review of O'Brien (2024) and to 10 that extent, I reviewed O'Brien 11 (2024) and materials associated 12 with that. I think we have been 13 going -- I'm going to ask for a 14 break at this point. We have been 15 going for an hour and a quarter, I 16 think, so I could do with five 17 minutes. 18 MR. TISI: Fine. That's okay. 19 We'll take a break now. I'm at a 20 breaking point. 21 - - - - 22 (A recess was taken at this time.) 23 - - - - 24</p>

<p style="text-align: right;">Page 146</p> <p>1 BY MR. TISI:</p> <p>2 Q. Back on the record.</p> <p>3 Dr. Kornak, we took about a half hour break</p> <p>4 and in the interim, I looked up two</p> <p>5 articles that you mentioned, I believe,</p> <p>6 discussing methods of imputation and they</p> <p>7 were number 29 and 32 of your CV. One</p> <p>8 titled "Bayesian k-space-time</p> <p>9 reconstruction of MR spectroscopic imaging</p> <p>10 for enhanced resolution."</p> <p>11 And the second one is</p> <p>12 "K-Bayes reconstruction for perfusion MRI</p> <p>13 II: Modeling and technical development,"</p> <p>14 both in 2010. Those were the studies you</p> <p>15 referred to?</p> <p>16 A. Yes, I believe so.</p> <p>17 Q. Okay. Would it surprise you</p> <p>18 that the word "imputation" isn't even used</p> <p>19 in these articles?</p> <p>20 A. No, it wouldn't surprise me.</p> <p>21 Q. All right. Let's go --</p> <p>22 A. I would say that the uses</p> <p>23 of --</p> <p>24 Q. No question.</p>	<p style="text-align: right;">Page 148</p> <p>1 Bayesian analysis in general, but that is</p> <p>2 missing data work --</p> <p>3 Q. Okay. Well --</p> <p>4 A. The question you asked, I did</p> <p>5 not do any specific papers about, they</p> <p>6 appear elsewhere. If you want to check the</p> <p>7 record on that, that's fine.</p> <p>8 Q. Doctor, I'm going to check</p> <p>9 the record as I do all the time. My</p> <p>10 question, I'm going to ask you again, is in</p> <p>11 any of your published work, articles,</p> <p>12 whatever, have you discussed the analytical</p> <p>13 tool of multiple imputation or single</p> <p>14 imputation as a method for dealing with</p> <p>15 missingness, not whether you used it, but</p> <p>16 whether you discuss when it's appropriate</p> <p>17 and under what circumstances?</p> <p>18 A. Well, the answer to that is</p> <p>19 going to be yes, because when you use it --</p> <p>20 unfortunately, this is not what O'Brien</p> <p>21 (2024) do, they don't justify why they're</p> <p>22 using it in their particular situation and</p> <p>23 whether it's appropriate. But whenever</p> <p>24 we -- I have been involved in using it in</p>
<p style="text-align: right;">Page 147</p> <p>1 A. The use of imputation -- I</p> <p>2 would need to qualify my answer --</p> <p>3 Q. No, but I asked you the</p> <p>4 question before, my question was not</p> <p>5 qualified. My question is, in any of your</p> <p>6 published literature, did you ever talk</p> <p>7 about the appropriateness of the methods of</p> <p>8 imputation to deal with missingness?</p> <p>9 A. I --</p> <p>10 Q. And your answer was -- your</p> <p>11 answer was in those two studies. The</p> <p>12 record will be what the record will be --</p> <p>13 A. No, we can check the record,</p> <p>14 because --</p> <p>15 Q. That's okay.</p> <p>16 A. -- what the record would say</p> <p>17 was you asked me if there was any methods</p> <p>18 papers that I did that involved missing</p> <p>19 data and methods development. That was the</p> <p>20 answer that these two papers were for and</p> <p>21 these two papers do. If you look, the</p> <p>22 approach that's taken is expectation</p> <p>23 maximization. I'm not even completely sure</p> <p>24 that I used the words there, it's part of</p>	<p style="text-align: right;">Page 149</p> <p>1 multiple imputation approaches or any way</p> <p>2 of dealing with missing data, I want to</p> <p>3 discuss those, the limitations of using</p> <p>4 those approaches and wherever possible to</p> <p>5 do sensitivity analysis. Again, O'Brien</p> <p>6 (2024) did not do that.</p> <p>7 Q. Okay. Move to strike.</p> <p>8 I would like to show you, we</p> <p>9 were talking before the break about the</p> <p>10 qualifications of the various authors to do</p> <p>11 and look at the data using the kinds of</p> <p>12 methods that they use in O'Brien (2024).</p> <p>13 Do you remember that testimony?</p> <p>14 A. Yeah, I remember that.</p> <p>15 Q. Okay. I would like to show</p> <p>16 you Exhibit No. 14, which is a -- do you</p> <p>17 know what International Agency on the</p> <p>18 Research for Cancer is?</p> <p>19 A. Yes, I know of them.</p> <p>20 - - - - -</p> <p>21 (IARC Monographs on the</p> <p>22 Identification of Carcinogenic</p> <p>23 Hazards to Humans marked Kornak</p> <p>24 Exhibit 14 for identification.)</p>

<p style="text-align: right;">Page 150</p> <p>1 - - - - -</p> <p>2 BY MR. TISI:</p> <p>3 Q. You know IARC, have you been</p> <p>4 involved in IARC? Have you ever been</p> <p>5 involved with IARC in any way?</p> <p>6 A. No. I mean, not directly. I</p> <p>7 may have been indirectly through my other</p> <p>8 work in cancer research, but not directly.</p> <p>9 Q. But you have to be actually</p> <p>10 asked to be a member of an IARC panel, you</p> <p>11 know that, right?</p> <p>12 A. I don't know what their</p> <p>13 methods are for bringing members onto the</p> <p>14 panel, I don't know.</p> <p>15 Q. You would agree with me that</p> <p>16 IARC is considered to be a reputable and</p> <p>17 important international organization with</p> <p>18 respect to the study of cancer and risk</p> <p>19 factors?</p> <p>20 A. I think it's an established</p> <p>21 agency in that field in terms of cancer</p> <p>22 research, yes.</p> <p>23 Q. Okay. By the way, do you</p> <p>24 know in this past week -- first of all, do</p>	<p style="text-align: right;">Page 152</p> <p>1 and with asbestos was a definite ovarian</p> <p>2 carcinogen. You understand that to be</p> <p>3 true, right?</p> <p>4 MS. LEHMAN: And I'm going to</p> <p>5 object. This is beyond the scope</p> <p>6 of his report.</p> <p>7 MR. TISI: Well, he said he</p> <p>8 looked at it, so I'm asking him</p> <p>9 that question. You understand that</p> <p>10 that -- that's what they concluded,</p> <p>11 right?</p> <p>12 THE WITNESS: I think you</p> <p>13 froze in the middle of the</p> <p>14 question, so I didn't get it.</p> <p>15 BY MR. TISI:</p> <p>16 Q. You understand that that's</p> <p>17 what they concluded that talc without</p> <p>18 asbestos is a probable ovarian carcinogen</p> <p>19 and with asbestos was a definite ovarian</p> <p>20 carcinogen. You understand that that was</p> <p>21 the conclusion of the IARC panel that was</p> <p>22 asked to look at this question, true?</p> <p>23 MS. LEHMAN: And I would,</p> <p>24 again, object as this is beyond the</p>
<p style="text-align: right;">Page 151</p> <p>1 you know that both Dr. O'Brien and Dr.</p> <p>2 Wentzensen were asked to be part of this</p> <p>3 particular panel because of their</p> <p>4 expertise, correct?</p> <p>5 MS. LEHMAN: Object to form.</p> <p>6 THE WITNESS: I know that</p> <p>7 from -- I think you were going to</p> <p>8 go start talking about the press</p> <p>9 release, the recent -- that came</p> <p>10 out in the last couple of days, but</p> <p>11 their names were on there, so they</p> <p>12 were on the panel. I don't know if</p> <p>13 they were asked to go on or whether</p> <p>14 they asked if they could go on. I</p> <p>15 don't know the process for their</p> <p>16 constructing panels.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Well, since you talked about</p> <p>19 the press release that came out in the past</p> <p>20 week, you do know that the panel upon which</p> <p>21 these authors, who were authors of multiple</p> <p>22 Sister Study publications, were part of a</p> <p>23 panel that determined on talc without</p> <p>24 asbestos was a probable ovarian carcinogen</p>	<p style="text-align: right;">Page 153</p> <p>1 scope of his report.</p> <p>2 THE WITNESS: Yeah, I mean, I</p> <p>3 would agree that -- I'm certainly</p> <p>4 not -- but my understanding is that</p> <p>5 from this paper that it moved from</p> <p>6 2B to 2A, so from possible to</p> <p>7 probable. Although, I looked at</p> <p>8 that document and I didn't see any</p> <p>9 new data or information or new</p> <p>10 publications that they took into</p> <p>11 account to update this decision.</p> <p>12 So I don't see any real reason --</p> <p>13 it doesn't update my opinions --</p> <p>14 BY MR. TISI:</p> <p>15 Q. Well --</p> <p>16 A. I don't see any reason -- any</p> <p>17 justification for changing from the</p> <p>18 previous stance.</p> <p>19 Q. So let's look at that for a</p> <p>20 moment. Would you look at -- actually,</p> <p>21 this is not in your book, since it came out</p> <p>22 after your book was mailed to you, but if</p> <p>23 we look at what I would like to have marked</p> <p>24 as Exhibit No. 28. It's the last, if you</p>

<p style="text-align: right;">Page 154</p> <p>1 look at page 15, can you put up Exhibit 2 No. 28, please? It says -- and this is 3 from Lancet, the Lancet publication, "Since 4 Volume 93, more consistent positive 5 associations for ever-use versus never-use 6 have been reported in pooled cohort studies 7 and case-control studies, including 8 evidence of exposure-response relationship 9 with frequency or duration of use." 10 Do you see that? 11 A. I see that's what it states 12 there, yes. 13 Q. And they have footnotes 14 there, right? 15 A. They have references 16 presumably to publications, yes. 17 Q. And one of those footnotes is 18 O'Brien (2020), which you said showed no 19 association, true? 20 A. So, again, like, you know, 21 that's O'Brien (2020). It's -- I've 22 already taken that into account in my 23 opinions and it suddenly doesn't lead to 24 reliable information about an association.</p>	<p style="text-align: right;">Page 156</p> <p>1 with O'Brien's prior work, right? 2 MS. LEHMAN: Object to form. 3 BY MR. TISI: 4 Q. And you refer to on page -- 5 on paragraph 25B. Do you see that? 6 A. In 25B, I see that I'm just 7 stating that O'Brien (2020) uses data on 8 ovarian cancer incidence from 2003 through 9 September 2017 and estimates a hazard ratio 10 summarizing an association between genital 11 talc use and ovarian cancer of 1.02 for 12 their point estimate with a 95 percent 13 confidence interval spanning 0.76 through 14 1.38. I don't see any discussion -- 15 Q. And you said that the 16 ultimate conclusions of O'Brien (2024) was 17 inconsistent with an association, true? 18 That's the whole point of paragraph 25 -- 19 excuse me -- yeah, 25. 20 A. No, I think what I'm pointing 21 out here in particular, I'm not -- I would 22 have to read here your statement to say 23 whether I agree or disagree -- 24 Q. My point is --</p>
<p style="text-align: right;">Page 155</p> <p>1 And I notice the clear omission of O'Brien 2 (2024) from those. 3 Q. Well, I'm going to move to 4 strike. My question was in your report, 5 you said repeatedly that the results that 6 show a positive association in O'Brien 7 (2024) was inconsistent with O'Brien's 8 prior work showing no association, correct? 9 MS. LEHMAN: Object to form. 10 THE WITNESS: I don't remember 11 having -- are you saying specific 12 words that I said or just anything 13 -- 14 BY MR. TISI: 15 Q. Yeah, it says -- 16 A. Can we go to it? I want to 17 make sure -- I just want to make sure I 18 answer you correctly, so if we could to the 19 actual part of the report. 20 Q. Sure. I'm happy to do it. 21 You had said previously that one of the 22 things that, on page 12 of your report, 23 Exhibit 1, you said that O'Brien (2024) 24 which showed an association is inconsistent</p>	<p style="text-align: right;">Page 157</p> <p>1 A. Can I just finish here? I 2 just -- 3 Q. Sure. I thought you were -- 4 A. What I'm saying here in 25, 5 I'm just trying to answer your question is 6 that O'Brien (2024), the prospective 7 analysis, their clean analyses is 8 prospective that avoids the risk of recall 9 bias, of making up data, of imputing data 10 or of correcting data and all of that stuff 11 gives you a hazard ratio of as close to one 12 and a 95 percent confidence interval is 13 very -- it is quite right, between .79 and 14 1.33 and that's consistent with what 15 O'Brien (2024) reports, yes. 16 Q. And O'Brien (2024) as 17 described by O'Brien and others in the IARC 18 document printed in Lancet says that that 19 supports an association, true? 20 MS. LEHMAN: Object to form. 21 THE WITNESS: Let's go -- can 22 we go to that document if you want 23 me to -- 24</p>

<p style="text-align: right;">Page 158</p> <p>1 BY MR. TISI:</p> <p>2 Q. Yeah, sure, go back to</p> <p>3 Exhibit number -- Jeff, can you go back to</p> <p>4 Exhibit No. 28, please, paragraph 15. It</p> <p>5 says "Since more consistent positive</p> <p>6 associations for ever-use versus never-use</p> <p>7 have been reported in pooled cohort studies</p> <p>8 and case-control studies including evidence</p> <p>9 of exposure-response relationship with</p> <p>10 frequency and duration of use."</p> <p>11 And as part of that, they</p> <p>12 actually cite O'Brien (2020), true?</p> <p>13 A. They do indeed cite O'Brien</p> <p>14 (2020). I disagree that O'Brien (2020)</p> <p>15 demonstrates a reliable association between</p> <p>16 talc use and ovarian cancer.</p> <p>17 Q. Okay. Let's -- so let me see</p> <p>18 if I can wrap this whole thing up.</p> <p>19 Previously, before the O'Brien (2024) study</p> <p>20 was published, the J&J lawyers in pleadings</p> <p>21 in this court where this case is pending</p> <p>22 have called these NIH studies preeminent.</p> <p>23 Do you recall that they are preeminent in</p> <p>24 their field?</p>	<p style="text-align: right;">Page 160</p> <p>1 This is --</p> <p>2 Q. Do you agree --</p> <p>3 MS. LEHMAN: Let him finish.</p> <p>4 Let him finish.</p> <p>5 THE WITNESS: This is just</p> <p>6 kind of a publication, a</p> <p>7 commentary, I don't know what you</p> <p>8 want to call it. It's stating what</p> <p>9 it says. It doesn't seem to have</p> <p>10 gone in-depth to try to really get</p> <p>11 at the biostatistical issues that</p> <p>12 are going on here, but it is just a</p> <p>13 short a summary, so I don't know</p> <p>14 what they have in mind.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Let's talk about the</p> <p>17 peer-review process and publication of this</p> <p>18 study and the reception that it got. We</p> <p>19 talked about the authors and their</p> <p>20 qualifications and engagement in --</p> <p>21 A. Sorry, which paper are we</p> <p>22 talking about, just so I make sure we're on</p> <p>23 the same page?</p> <p>24 Q. We talked about the authors,</p>
<p style="text-align: right;">Page 159</p> <p>1 MS. LEHMAN: Object to form.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Based upon what you've seen</p> <p>4 and what we've gone over today.</p> <p>5 A. I mean, to my mind, I don't</p> <p>6 know what, like, you mean by "preeminent,"</p> <p>7 actually.</p> <p>8 Q. It was J&J's words. So I'm</p> <p>9 going to tell you when O'Brien (2020) was</p> <p>10 out before O'Brien (2024), J&J told the</p> <p>11 court that these particular authors,</p> <p>12 Wentzensen, O'Brien, Sandler were</p> <p>13 preeminent. Do you agree that they are</p> <p>14 preeminent in their field?</p> <p>15 A. I'm not --</p> <p>16 MS. LEHMAN: Object to form.</p> <p>17 THE WITNESS: I don't know</p> <p>18 what -- I don't know for sure what</p> <p>19 Johnson & Johnson said and I'm not</p> <p>20 responsible for their words and I'm</p> <p>21 not able to --</p> <p>22 BY MR. TISI: --</p> <p>23 Q. So you disagree?</p> <p>24 A. -- say I agree or disagree.</p>	<p style="text-align: right;">Page 161</p> <p>1 you know which authors, okay, in the past</p> <p>2 45 minutes or so, we talked about</p> <p>3 Wentzensen, O'Brien, Sandler --</p> <p>4 A. Okay. Are we talking about a</p> <p>5 specific paper though or are we just --</p> <p>6 Q. We're going to in a moment --</p> <p>7 A. -- talking as a group?</p> <p>8 Q. You need to follow my</p> <p>9 question, okay? I asked you about their</p> <p>10 qualifications.</p> <p>11 A. Okay.</p> <p>12 Q. I asked you about their</p> <p>13 qualifications. Now, I want to talk about</p> <p>14 O'Brien (2024). Okay?</p> <p>15 A. Okay.</p> <p>16 Q. All right. Now, first of</p> <p>17 all, we talked about this before, O'Brien</p> <p>18 (2024) was published in a peer-reviewed</p> <p>19 journal, correct?</p> <p>20 A. Yes.</p> <p>21 MS. LEHMAN: Asked and</p> <p>22 answered.</p> <p>23 BY MR. TISI:</p> <p>24 Q. What is peer review?</p>

<p style="text-align: right;">Page 162</p> <p>1 A. So peer review is a process, 2 I will admit it's an imperfect one, but 3 it's the best that we have in academia, 4 where people submit their scientific works 5 to a journal, the journal, perhaps an 6 associate editor or editor sends it out to 7 two or three reviewers particularly that 8 they think should be able to to review the 9 paper. And then the reviewers spend some 10 time reviewing the paper. They give their 11 opinions as to whether it should be 12 accepted or not accepted, and anything they 13 think needs correcting and then that goes 14 back to the authors and if there are 15 corrections required, the authors will try 16 and do that. And so -- and it then goes 17 back to the reviewers and then the paper is 18 typically either accepted or rejected. 19 Q. Okay. So it's a process, 20 it's a scientific process that's well 21 accepted in the scientific community even 22 with its imperfections, correct? 23 MS. LEHMAN: Object to form. 24 THE WITNESS: I mean, again,</p>	<p style="text-align: right;">Page 164</p> <p>1 little bit of what if. What if it was 2 20 percent, what if it was 30 percent, or 3 whatever, they're trying out a few things 4 and saying what would change. I would sort 5 of reserve, I wouldn't call that -- 6 Q. Well, you know, move to 7 strike your answer, because my question 8 was, the question of a quantitative bias 9 analysis was clearly set out in the 10 article. It would be hard to miss it, it's 11 in the title, true? 12 MS. LEHMAN: Objection to 13 form. 14 THE WITNESS: I already agreed 15 in quantitative bias analysis is in 16 the title. I would disagree that 17 it's really an analysis -- 18 BY MR. TISI: 19 Q. I understand. I'm not 20 debating you right now about what they did 21 and what they didn't do. I'm talking about 22 the peer-review process. Is there any 23 possibility in your mind that the peer 24 reviewers could have missed the methodology</p>
<p style="text-align: right;">Page 163</p> <p>1 it's kind of -- I don't know, 2 there's definitely a lot of debate 3 about whether the process should be 4 changed and should be improved, but 5 as it stands, this is the process 6 that we have for peer-reviewed 7 journals and, like I said, I think 8 it's accepted as the best we have 9 available to us right now. 10 BY MR. TISI: 11 Q. And you would agree with me 12 that the quantitative bias analysis that 13 was conducted by these NIH scientists for 14 O'Brien (2024) was central to their 15 article, correct? In fact, it appears in 16 the title of the article, correct? 17 A. I agree that it appears in 18 the title of the article. I agree that it 19 is a major component of their paper. It's 20 kind of, let's say, the last third or 21 simply make that. I actually disagree with 22 it calling it a quantitative bias analysis. 23 I think that's taking it a little further, 24 because really all they're doing is doing a</p>	<p style="text-align: right;">Page 165</p> <p>1 point of this study, particularly since 2 it's in the title of the article? 3 A. Oh, absolutely, I think they 4 did miss it, yeah. 5 Q. Okay. All right. Now, the 6 article, so you think that the peer 7 reviewers and the journal completely missed 8 it? 9 A. Yes, I do. Yeah, I mean, 10 it's -- they missed it. I don't know 11 what -- I'm surprised that a journal would 12 let that go. I blame it probably on the 13 associate editors for not picking the right 14 range of reviewers, but nobody picked up on 15 the biostatistical problems in this paper. 16 Q. Okay. I pulled the 17 publication history from the article, for 18 this article, and it's Exhibit No. 24 in 19 your book. It was received -- 20 A. I'm sorry, just give me a 21 moment, because the end is taking -- 22 - - - - - 23 (Publication History marked 24 Kornak Exhibit 24 for</p>

<p style="text-align: right;">Page 166</p> <p>1 identification.)</p> <p>2 -----</p> <p>3 BY MR. TISI:</p> <p>4 Q. It's right on the screen.</p> <p>5 A. Yes, the pages through the</p> <p>6 binder.</p> <p>7 Q. I'll blame that on Jeff.</p> <p>8 A. All right.</p> <p>9 Q. If you look at the very</p> <p>10 bottom, it's on the screen as well, it was</p> <p>11 received for publication in September of</p> <p>12 2023, revised in January 2024. Accepted</p> <p>13 for publication in March of 2024 and</p> <p>14 published in May of 2024. So this whole</p> <p>15 process took about eight or nine months,</p> <p>16 correct?</p> <p>17 A. That's not unusual for --</p> <p>18 Q. And you claim that the</p> <p>19 authors, the peer reviewers and everybody</p> <p>20 involved has missed it, right?</p> <p>21 A. Sorry, what is it that you're</p> <p>22 talking about specifically?</p> <p>23 Q. The methodology concerns that</p> <p>24 you identify in your report, Exhibit 1.</p>	<p style="text-align: right;">Page 168</p> <p>1 A. Remind me of which number</p> <p>2 that is.</p> <p>3 Q. That is number eight. On</p> <p>4 page 14, it says that the publication was</p> <p>5 "Supported by an Intramural Research</p> <p>6 Program of the National Institute of</p> <p>7 Environmental Health Sciences, National</p> <p>8 Institutes of Health."</p> <p>9 Do you see that?</p> <p>10 A. On page 14, where are we</p> <p>11 looking at? Sorry.</p> <p>12 Q. Support.</p> <p>13 A. Under support.</p> <p>14 Q. The second column at the very</p> <p>15 end of the article.</p> <p>16 Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. All right. And so it's</p> <p>19 supported through an NIH grant, correct?</p> <p>20 A. Intramural grant, so that's</p> <p>21 within the NIH. So I don't know that it's</p> <p>22 a typical NIH grant --</p> <p>23 Q. Correct.</p> <p>24 A. -- paid for by --</p>
<p style="text-align: right;">Page 167</p> <p>1 A. They absolutely missed it,</p> <p>2 yes.</p> <p>3 Q. Okay.</p> <p>4 A. Well, I don't know if there's</p> <p>5 a comment and the associate editor ignored</p> <p>6 it, I don't know about the inner workings,</p> <p>7 but the final paper has these flaws in it.</p> <p>8 I mean --</p> <p>9 Q. Do you have any reason -- I'm</p> <p>10 sorry. Sorry. I apologize, sir, I'm not</p> <p>11 intentionally talking over you.</p> <p>12 A. No problem.</p> <p>13 Q. Do you have any reason to</p> <p>14 believe that these authors did not respond</p> <p>15 to every one of the peer reviewer comments</p> <p>16 that were made about this paper?</p> <p>17 A. I don't have any reason to</p> <p>18 believe that. What I believe is that</p> <p>19 reviewers looked at the paper on the</p> <p>20 surface level and did not dig in and pick</p> <p>21 up on these very clear problems in the</p> <p>22 biostatistical methods.</p> <p>23 Q. Now, if you go back to</p> <p>24 O'Brien (2024) --</p>	<p style="text-align: right;">Page 169</p> <p>1 Q. Correct. Do you understand</p> <p>2 that intramural grants, publications that</p> <p>3 are as a result of an intramural grant by</p> <p>4 NIH scientists when they publish a paper,</p> <p>5 in addition to undergoing peer review by</p> <p>6 the journal, the article is actually</p> <p>7 submitted to the NIH for their approval?</p> <p>8 A. You know, I don't know what</p> <p>9 process they actually go through in the</p> <p>10 NIH, but I don't know what they're looking</p> <p>11 for, and I would not call it peer review.</p> <p>12 Peer review is when it goes out to</p> <p>13 somebody, to blinded reviewers that are</p> <p>14 assigned by a journal, so that's not --</p> <p>15 this is not peer review. It may be an</p> <p>16 extra stage of review. And I don't know</p> <p>17 what they're reviewing it for, just whether</p> <p>18 there are things that the NIH clearly</p> <p>19 doesn't agree with. I mean, you can see,</p> <p>20 there's a disclaimer here that the National</p> <p>21 Institutes of Health holds -- has no role</p> <p>22 in the design, conduct, or interpretation</p> <p>23 of this study. That's typical of the NIH,</p> <p>24 they don't take responsibility for any</p>

<p style="text-align: right;">Page 170</p> <p>1 studies that they hand out grants here.</p> <p>2 Q. I'm sorry, you froze. Did I</p> <p>3 interrupt your answer? I apologize, you</p> <p>4 froze.</p> <p>5 A. No, you didn't interrupt.</p> <p>6 I'm fine.</p> <p>7 Q. My point here is this, in</p> <p>8 addition to the normal peer review to</p> <p>9 appear in a publication, this article had</p> <p>10 to be submitted by the authors to the NIH</p> <p>11 for its approval, correct?</p> <p>12 A. I mean, I understand there's</p> <p>13 some kind of process, I don't know what</p> <p>14 that process entails, but I would not call</p> <p>15 it peer review, no, sir.</p> <p>16 Q. Okay. But NIH clearly knew</p> <p>17 about it and clearly had the ability to</p> <p>18 comment on this paper, true?</p> <p>19 MS. LEHMAN: Object to form.</p> <p>20 THE WITNESS: You know, I</p> <p>21 really don't know if that's</p> <p>22 correct. Because, again, I don't</p> <p>23 know what -- whether they're</p> <p>24 reviewing it with respect to</p>	<p style="text-align: right;">Page 172</p> <p>1 MS. LEHMAN: Object to form.</p> <p>2 THE WITNESS: I didn't hear --</p> <p>3 BY MR. TISI:</p> <p>4 Q. Feature the article, it</p> <p>5 highlighted the article and published it on</p> <p>6 the NIH website for the world to see</p> <p>7 because it was an important study, true?</p> <p>8 MS. LEHMAN: Object to form.</p> <p>9 THE WITNESS: I think that's a</p> <p>10 stretch to make that conclusion</p> <p>11 there.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Okay.</p> <p>14 A. Now, at UCSF, in our</p> <p>15 department, people write papers and we put</p> <p>16 out little sort of statements as kind of a</p> <p>17 sales pitch for the research that you do.</p> <p>18 And I don't know that the NIH thing was</p> <p>19 anything beyond that really.</p> <p>20 Q. Okay. Well, how many of your</p> <p>21 papers have been featured by UCSF,</p> <p>22 featured, put on the website and saying</p> <p>23 this is what you need to pay attention to?</p> <p>24 A. I really don't know and I</p>
<p style="text-align: right;">Page 171</p> <p>1 whether it violates a condition of</p> <p>2 an NIH grant that is awarded</p> <p>3 intramurally, I don't know the</p> <p>4 process, but --</p> <p>5 BY MR. TISI:</p> <p>6 Q. Well, the NIH -- I'm sorry.</p> <p>7 A. The NIH, again, it won't take</p> <p>8 responsibility for the work in there. It</p> <p>9 won't sort of -- so if it's not going to</p> <p>10 take responsibility, I don't see how it's</p> <p>11 kind of a real review of the science. It</p> <p>12 may be a review that they haven't broken</p> <p>13 any NIH rules.</p> <p>14 Q. You're speculating --</p> <p>15 A. No, I don't know. I don't</p> <p>16 have internal mechanisms, so it's outside</p> <p>17 my scope in a way.</p> <p>18 Q. But the NIH didn't have to</p> <p>19 feature the article, did it, which you know</p> <p>20 it did?</p> <p>21 A. What's that?</p> <p>22 Q. The NIH didn't have to</p> <p>23 feature the article which you know it did,</p> <p>24 true?</p>	<p style="text-align: right;">Page 173</p> <p>1 think there may have been one or two, I'm</p> <p>2 not sure, but I tend to be -- try to be</p> <p>3 modest. So often to get -- the department</p> <p>4 kind of solicits you to try and send them</p> <p>5 information when you've published a paper.</p> <p>6 I tend to not really want to do it. I</p> <p>7 don't think it helps my academic career and</p> <p>8 I don't love to be featured on websites, to</p> <p>9 be honest.</p> <p>10 Q. Let's look at what the NIH</p> <p>11 actually said about the study, which it</p> <p>12 didn't have to do, we agree. Let's look at</p> <p>13 Exhibit No. 4. This is a publication on</p> <p>14 the NIH website highlighting the --</p> <p>15 highlighting O'Brien (2024). And it says</p> <p>16 "New study by NIEHS scientists provides</p> <p>17 compelling evidence that genital talc use</p> <p>18 is associated with an increased risk of</p> <p>19 ovarian cancer," true?</p> <p>20 A. It's true that that is what's</p> <p>21 stated there, yes.</p> <p>22 -----</p> <p>23 (Environmental Factor</p> <p>24 Article from NIH marked Kornak</p>

<p style="text-align: right;">Page 174</p> <p>1 Exhibit 4 for identification.)</p> <p>2 - - - - -</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. But --</p> <p>5 A. I don't agree with the</p> <p>6 statement, but it is stated there.</p> <p>7 Q. I understand, but you've</p> <p>8 disagreed with the peer reviewers, you've</p> <p>9 disagreed with the journal, and now you're</p> <p>10 disagreeing with the NIH, correct?</p> <p>11 MS. LEHMAN: Object to form.</p> <p>12 THE WITNESS: You know, what</p> <p>13 you say explicitly is correct, I'm</p> <p>14 disagreeing with all of them --</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay.</p> <p>17 A. -- but I believe that most of</p> <p>18 them have just taken what O'Brien said on</p> <p>19 their paper at face value without really</p> <p>20 digging in there. So if you don't look at</p> <p>21 the paper and you don't examine the</p> <p>22 analysis and you just say, oh, they did</p> <p>23 recall bias, great. Oh, they did</p> <p>24 corrections, great. But they're not great,</p>	<p style="text-align: right;">Page 176</p> <p>1 what you're saying, I followed there, and</p> <p>2 then I got lost, I didn't see. I see the</p> <p>3 quote --</p> <p>4 Q. Actually, it says "An</p> <p>5 especially unique aspect of the study was</p> <p>6 the use of quantitative bias analysis to</p> <p>7 assess the impact of potential errors in</p> <p>8 reporting use of intimate care products,</p> <p>9 including possible differential reporting</p> <p>10 related to being diagnosed or not diagnosed</p> <p>11 with cancer," true?</p> <p>12 A. I'm sorry. You were reading,</p> <p>13 I thought, from the bottom paragraph and</p> <p>14 you went up a bit --</p> <p>15 Q. No, I'm not. Let's look at</p> <p>16 the paragraph I've highlighted on the</p> <p>17 screen.</p> <p>18 A. Sorry.</p> <p>19 Q. The highlighted paragraph on</p> <p>20 the screen focuses on the quantitative bias</p> <p>21 analysis performed by the authors and</p> <p>22 highlights it as a particularly unique, I</p> <p>23 think that is the word they use, rigorous</p> <p>24 and unique feature of the study, true?</p>
<p style="text-align: right;">Page 175</p> <p>1 because they're flawed and they're made up</p> <p>2 and they're artificial.</p> <p>3 Q. Okay. So now let's look at</p> <p>4 what the -- the NIH in it's brief summary</p> <p>5 here actually focuses on the methods, don't</p> <p>6 they?</p> <p>7 A. Can you point me to where you</p> <p>8 think they do?</p> <p>9 Q. Sure, it says, the third</p> <p>10 paragraph down, it says "This extensive</p> <p>11 analysis, conducted using information</p> <p>12 collected by the Sister Study cohort,</p> <p>13 revisits the association between intimate</p> <p>14 care products and cancer and incorporates</p> <p>15 rigorous adjustments for biases that might</p> <p>16 have affected the results of earlier</p> <p>17 studies. The study analyzed data from a</p> <p>18 cohort of women who were initially</p> <p>19 cancer-free who reported their intimate use</p> <p>20 of intimate care products like genital talc</p> <p>21 and douching over time. An especially</p> <p>22 unique aspect of the study was the use of</p> <p>23 quantitative bias analysis to assess --"</p> <p>24 A. I got the first sentence of</p>	<p style="text-align: right;">Page 177</p> <p>1 A. It's --</p> <p>2 MS. LEHMAN: Object to form.</p> <p>3 THE WITNESS: I didn't follow</p> <p>4 exactly the wording you said as you</p> <p>5 were reading it, but --</p> <p>6 BY MR. TISI:</p> <p>7 Q. Well, let's read it together</p> <p>8 --</p> <p>9 A. What is actually stated there</p> <p>10 in meaning, but I do not agree that that's</p> <p>11 a review of the methods that they used.</p> <p>12 They're just parroting what was in the --</p> <p>13 the authors said they did in the paper.</p> <p>14 There's nothing in there that implies in</p> <p>15 any way that these people understood what</p> <p>16 these methods were, that they were really</p> <p>17 just, correcting means flipping people over</p> <p>18 from one side to the other, that imputation</p> <p>19 means that you bring in the recall bias</p> <p>20 that you found in the data you've already</p> <p>21 collected and that you're making</p> <p>22 assumptions about things that you don't</p> <p>23 really know.</p> <p>24 Q. Okay.</p>

<p style="text-align: right;">Page 178</p> <p>1 A. So overall, no, I don't 2 believe -- 3 Q. So far -- 4 A. I don't believe that these 5 people have in any way examined the 6 analysis methods in the paper. 7 Q. Even though they said that, 8 right, even though they said that -- 9 A. They are just parroting what 10 is there in the paper -- 11 Q. Actually, they're not 12 parroting or quoting the paper at all, 13 look, I'm not fussing with you here. But 14 they say the cohort -- that this revisits 15 the association between intimate care 16 products and cancer and incorporates 17 rigorous adjustments for bias that might 18 have affected the results of earlier 19 studies. And then it goes on to say, 20 especially, "An especially unique aspect of 21 the study was the use of quantitative bias 22 analysis to assess the impact of potential 23 errors in reporting use of intimate care 24 products, including possible differential</p>	<p style="text-align: right;">Page 180</p> <p>1 BY MR. TISI: 2 Q. Let me rephrase it then -- 3 A. They did not go and actually 4 examine what the analyses are. 5 Q. Let me rephrase the 6 question -- 7 A. There's a common flaw in 8 reviewing papers where they just accept 9 that things at face value without actually 10 taking the time to see what really did go 11 on there. 12 Q. Let me rephrase the question 13 so that we get the "it" right, okay? 14 A. Okay. 15 Q. The peer reviewers did not 16 understand or fully appreciate the errors 17 in the methodology. The editors didn't 18 understand or appreciate the methodology. 19 The authors didn't understand or appreciate 20 the errors in methodology. The NIH didn't 21 understand or appreciate the errors in the 22 methodology. All of those people got it 23 wrong, right? 24 MS. LEHMAN: Object to form.</p>
<p style="text-align: right;">Page 179</p> <p>1 reporting related to being diagnosed or not 2 diagnosed with cancer," correct? 3 A. Again, those are the words 4 that these people write down. They are 5 just paraphrasing what is in the O'Brien 6 paper. You really want an analysis that 7 doesn't suffer from recall bias and so on, 8 go to the analysis in Table A2, that's 9 clear. 10 Q. Okay. Well, we're going to 11 talk about Table A2. I promise you, we're 12 going to get there. But so far, so far 13 okay, so far the peer reviewers missed it, 14 all the authors, including the 15 biostatistician, on the paper got it wrong 16 and NIH was just parroting what the authors 17 said, right? 18 MS. LEHMAN: Object to form. 19 THE WITNESS: I mean, I'm 20 going to -- again, when you say 21 "got it wrong," the "it" is kind of 22 some vague, nebulous thing, but 23 what they did do -- 24</p>	<p style="text-align: right;">Page 181</p> <p>1 THE WITNESS: So you've gone 2 back to got it wrong again -- 3 BY MR. TISI: 4 Q. They didn't appreciate the 5 errors in the methodology, correct? 6 A. They either didn't appreciate 7 or they ignored or they didn't have the 8 time to look into it in any depth, but they 9 took what O'Brien said at face value. All 10 I can say is that, again, I independently 11 reviewed the paper. Those flaws are there. 12 I clearly outline why they're flaws and -- 13 Q. So let's -- 14 ----- 15 (Stenographer clarification.) 16 ----- 17 THE WITNESS: I haven't had 18 anything disputing why the flaws 19 are there -- 20 MR. TISI: We'll get there. 21 THE WITNESS: Why there are 22 really flaws. 23 BY MR. TISI: 24 Q. We'll get there. One other</p>

<p style="text-align: right;">Page 182</p> <p>1 group that didn't understand or appreciate 2 the errors that you've identified is the 3 American Association of Clinical 4 Oncologists, true? 5 A. I think I would like you to 6 make the question more specific -- 7 Q. Okay. 8 A. -- I mean, in this group, 9 there's going to be a lot of people, I 10 don't know what all these people's 11 different opinions are, so -- 12 Q. Well, let's talk about 13 somebody else who missed it. Let's look at 14 Exhibit No. 5. 15 A. Okay. 16 ----- 17 (ASCO Publication marked 18 Kornak Exhibit 5 for 19 identification.) 20 ----- 21 BY MR. TISI: 22 Q. And this is a statement by 23 the American Society of Clinical Oncology. 24 Do you see that?</p>	<p style="text-align: right;">Page 184</p> <p>1 ASCO. 2 Q. She gives her phone number 3 and her email address. Did you reach out 4 to her and tell her, you don't think this 5 is a particularly good study, did you? 6 A. No, but I think -- I didn't 7 do that and, again, I've explained that I'm 8 not reaching out to people on the basis of 9 I have been asked to independently review 10 this paper and I assume I am under sort of 11 confidentiality constraints and I don't 12 want to break those. 13 Q. Are any of the -- are any of 14 the articles upon which you relied in 15 support of your position confidential? 16 They're all published literature, correct? 17 A. They are all published 18 literature, but if I start talking to 19 people about them, then it becomes -- then 20 I become -- I'm talking about the case and 21 I don't -- that's where I assume I'm 22 breaking confidentiality. 23 Q. Do you agree that, generally 24 speaking, the peer-review process and not</p>
<p style="text-align: right;">Page 183</p> <p>1 A. Yes, and I've seen this 2 previously. 3 Q. All right. And if you look 4 at page 4, "The American Society of 5 Clinical Oncology is committed to the 6 principle and the knowledge conquers 7 cancer. Together with the Association for 8 Clinical Oncology, ASCO represents nearly 9 50,000 oncology professionals who care for 10 people living with cancer." 11 Do you see that? 12 A. Yes. 13 Q. Okay. Now, if you go to the 14 front of the paper I just showed you, they 15 say this is -- go to page 1, please. This 16 is the ASCO perspective, the perspective of 17 the organization, true? 18 A. I mean, I don't think all 19 50,000 members of ASCO contributed to this 20 article. I would assume there was some 21 small group or maybe even just one person, 22 I don't know. Maybe it was just Naomi 23 Hagelund who is listed at the top that is 24 writing this in some way at the request of</p>	<p style="text-align: right;">Page 185</p> <p>1 the courtroom provides the best mechanism 2 for resolving scientific uncertainty 3 relating to methodologic analysis of 4 complex scientific issues? 5 A. Well, it depends what you 6 mean by "best" here, because what the 7 complex -- I don't know if peer review 8 really resolves complex scientific issues. 9 Peer review kind of, like, reviews the 10 paper to see if there are problems with the 11 paper, if it's flawed, but they're not -- 12 peer review doesn't try to resolve disputes 13 in science. 14 Q. Okay. So you would disagree 15 with that statement that the peer-review 16 process and not the courtroom is the best 17 mechanism for resolving scientific 18 uncertainties relating to methodologic 19 analysis of complex scientific data? 20 A. I think I said it depends and 21 that's what I'm sticking with, it really 22 depends on -- 23 Q. In this case, do you -- 24 A. I mean, it's like --</p>

<p style="text-align: right;">Page 186</p> <p>1 Q. In this case --</p> <p>2 A. I don't think either is the</p> <p>3 best approach --</p> <p>4 Q. Okay.</p> <p>5 A. -- of solving complex</p> <p>6 scientific questions.</p> <p>7 Q. Okay. Now, going back to</p> <p>8 Exhibit No. 5, the main takeaway of the</p> <p>9 article is from the perspective of ASCO,</p> <p>10 the organization, is "Genital talc use was</p> <p>11 found to be positively associated with the</p> <p>12 risk of ovarian cancer across multiple</p> <p>13 scenarios, even after adjusting for</p> <p>14 potential reporting biases and</p> <p>15 misclassification. The association was</p> <p>16 particularly strong among women who used</p> <p>17 talc frequently or especially during</p> <p>18 periods of specific hormonal changes or</p> <p>19 reproductive activity." Right?</p> <p>20 A. That is what it states, yes.</p> <p>21 Q. Okay. And they got it wrong</p> <p>22 too, they missed the methodologic flaws of</p> <p>23 the study, true?</p> <p>24 A. I don't think -- I mean, I</p>	<p style="text-align: right;">Page 188</p> <p>1 quite clearly that even with their belief</p> <p>2 that O'Brien (2024) was correct, when they</p> <p>3 talk about the significance, they talk</p> <p>4 about needing further research and</p> <p>5 potential reevaluation. These are all sort</p> <p>6 of qualified statements. So even from the</p> <p>7 journal that is backing the paper that</p> <p>8 they've published, they still have all</p> <p>9 these qualified statements in there.</p> <p>10 Q. All right. So with respect</p> <p>11 to the methodology, which is what you're</p> <p>12 here to talk about, on the next page it,</p> <p>13 says it "provides compelling evidence that</p> <p>14 genital talc use associated with an</p> <p>15 increased risk of ovarian cancer."</p> <p>16 Do you see that?</p> <p>17 A. I see that's written there.</p> <p>18 I don't agree with it.</p> <p>19 Q. And the last sentence says</p> <p>20 "They incorporate rigorous adjustments for</p> <p>21 biases that may have affected earlier</p> <p>22 studies."</p> <p>23 Do you see that?</p> <p>24 A. Again, I'm sorry. Yes, I see</p>
<p style="text-align: right;">Page 187</p> <p>1 can walk you through piece by piece here if</p> <p>2 you want --</p> <p>3 Q. We're going to, but they got</p> <p>4 it wrong?</p> <p>5 A. Like I said, I can walk you</p> <p>6 through piece by piece of what the problems</p> <p>7 are with this statement --</p> <p>8 Q. We're going to talk about it,</p> <p>9 sir --</p> <p>10 A. I'm not saying they're right</p> <p>11 or wrong. It's more complicated than that.</p> <p>12 I can walk you through the problems with</p> <p>13 the statement. Again, I think they took</p> <p>14 what's in O'Brien at face value and --</p> <p>15 first of all, there is no adjusting here</p> <p>16 for potential reporting biases. Adjusting</p> <p>17 in biostatistics means you include</p> <p>18 variables within your modeling and you</p> <p>19 adjust them within your modeling. There</p> <p>20 was no incorporation of these variables as</p> <p>21 adjustments in the model. That's not true.</p> <p>22 So it's just plain false. So, in that</p> <p>23 sense, yes, it's wrong.</p> <p>24 Even here, they point out</p>	<p style="text-align: right;">Page 189</p> <p>1 it actually says those words there.</p> <p>2 Q. Right. And so they --</p> <p>3 A. I don't agree with that.</p> <p>4 Q. And you disagree with it,</p> <p>5 right?</p> <p>6 A. I disagree that these are</p> <p>7 rigorous adjustments and I can be quite</p> <p>8 clear why, because their analyses are not</p> <p>9 all showing positive associations. In</p> <p>10 fact, the only ones that do are when they</p> <p>11 do all of the multiple imputation and when</p> <p>12 they do all -- there's a Scenario 3 where</p> <p>13 they flip everyone and then there's a</p> <p>14 multiple imputation where they bring in</p> <p>15 recall bias, but none of the other analyses</p> <p>16 have --</p> <p>17 Q. And Scenario 2 is when they</p> <p>18 say everybody is negative, right? Scenario</p> <p>19 2 is where everybody is a nonuser and then</p> <p>20 Scenario 3 is everybody is a user, right,</p> <p>21 and they did that to restore the range of</p> <p>22 the product --</p> <p>23 A. That's not correct. That's</p> <p>24 not correct.</p>

<p style="text-align: right;">Page 190</p> <p>1 Q. Okay. Well, we're going to 2 talk about that. But let's wrap this 3 section up. We've gone through the peer 4 review by JCO, the review by NIH -- oh, one 5 more issue. Actually, there is one more. 6 Let's look at Exhibit No. 6. You don't 7 address this in your report, but it's in 8 your -- it's actually in your materials 9 that you reviewed. There was an editorial 10 that actually accompanied this article, 11 correct? 12 A. I mean, there is this paper 13 here, you know, I don't know what -- that 14 it's -- I read, I think I read in one 15 deposition that it isn't really an 16 editorial, it's a letter to the editor, 17 but -- 18 Q. Whose deposition are you 19 referring to? 20 A. I think that was to Dr. 21 Diette. 22 Q. All right. So are you having 23 your own independent review of this 24 evidence or are you relying on Dr. Diette?</p>	<p style="text-align: right;">Page 192</p> <p>1 opinion. I'm just using -- if I 2 hadn't seen that, I would say yes, 3 this is an editorial. All I got 4 from that is that I'm not saying 5 that it isn't, I'm just saying I 6 don't know and that just raises 7 some doubt. But, no, I'm not 8 taking his opinion. 9 BY MR. TISI: 10 Q. Okay. So this is -- I will 11 suggest to you that this is an invited 12 editorial by the authors, but whether it is 13 or it is not, this is an editorial 14 submitted to the journal which published 15 the paper which talks about its relevance, 16 true? 17 A. It's a paper that talks about 18 what the authors perceive or want to 19 perceive from reading the O'Brien paper. 20 Q. And one of the authors is, as 21 you know, is actually and has been 22 published in the world of talc and ovarian 23 cancer, correct, Dr. Terry? 24 A. Now, is that a name we've</p>
<p style="text-align: right;">Page 191</p> <p>1 A. No, I did my own independent 2 review, I'm just -- I would like to answer 3 the question -- 4 THE STENOGRAPHER: Hold on, 5 please. Please. 6 THE WITNESS: Sorry. 7 THE STENOGRAPHER: You're 8 talking over each other and we had 9 and objection. I think there was 10 an objection. I didn't hear the 11 objection -- 12 MS. LEHMAN: Yes, I object to 13 the form of the question. 14 ----- 15 (Harris 2024 Article marked 16 Kornak Exhibit 6 for 17 identification.) 18 ----- 19 BY MR. TISI: 20 Q. Let's actually -- 21 MS. LEHMAN: Let him finish. 22 He hasn't answered. 23 THE WITNESS: Yeah, I'm not -- 24 I'm not taking Dr. Diette's</p>	<p style="text-align: right;">Page 193</p> <p>1 already come across on one of the 2 publications? 3 Q. Yeah. It was actually in the 4 Lancet article. 5 A. Okay. 6 Q. And if you go to Exhibit 7 No. 7, there is an article "Genital Powder 8 Use and Risk of Ovarian Cancer: A pooled 9 Analysis of 8,525 Cases and 9,855 10 Controls." 11 Do you see that? 12 A. Okay. I'm sorry, you're 13 going to a little fast. I thought we were 14 on the Harris paper. We're moving to a 15 different one? 16 Q. No, this is, one of the 17 authors in Harris is Terry, correct? 18 A. Yes. 19 ----- 20 (Terry Paper 2013 marked 21 Kornak Exhibit 7 for 22 identification.) 23 ----- 24</p>

<p style="text-align: right;">Page 194</p> <p>1 BY MR. TISI:</p> <p>2 Q. And Terry actually has</p> <p>3 written in this space, this isn't somebody</p> <p>4 who just parachuted in with no knowledge of</p> <p>5 what the background of talc and ovarian</p> <p>6 cancer was, true?</p> <p>7 A. Yeah, this person has been</p> <p>8 involved in the field.</p> <p>9 Q. Okay. And she's publishing</p> <p>10 here on the behalf of the American Cancer</p> <p>11 Association Consortium, do you see that, at</p> <p>12 the very bottom?</p> <p>13 MS. LEHMAN: Object to form.</p> <p>14 THE WITNESS: I don't know if</p> <p>15 she is -- I mean, yeah, that the</p> <p>16 author list ends with on behalf of</p> <p>17 the Ovarian Cancer Association</p> <p>18 Consortium, but we have to be</p> <p>19 careful as to what that means. I'm</p> <p>20 also part of, like, various</p> <p>21 consortiums where that kind of</p> <p>22 ending appears on the author list.</p> <p>23 But it doesn't mean that there's</p> <p>24 whatever association that we're</p>	<p style="text-align: right;">Page 196</p> <p>1 O'Brien (2024) paper, also focuses on</p> <p>2 unique methods actually performed by</p> <p>3 O'Brien (2024), correct?</p> <p>4 MS. LEHMAN: Object to form.</p> <p>5 THE WITNESS: I don't think it</p> <p>6 does. I think it's a -- it doesn't</p> <p>7 focus on that. It's kind of an</p> <p>8 overall kind of summary thing and,</p> <p>9 you know, again, they sort of kind</p> <p>10 of paraphrase what the authors of</p> <p>11 the paper said they do, but they</p> <p>12 don't go into any detail as what</p> <p>13 these reclassification exposures</p> <p>14 are. They don't talk about why is</p> <p>15 80 percent a good exposure for one</p> <p>16 group whereas is 90 percent a good</p> <p>17 exposure for a reclassification for</p> <p>18 another group. Even the takeaway</p> <p>19 here, they're very kind of vague</p> <p>20 about how far they're willing to go</p> <p>21 with what's stated here. They just</p> <p>22 say these data suggest that people</p> <p>23 who are at risk for ovarian cancer</p> <p>24 should be made aware of the</p>
<p style="text-align: right;">Page 195</p> <p>1 publishing on behalf of takes</p> <p>2 responsibility for the paper.</p> <p>3 BY MR. TISI:</p> <p>4 Q. So let's go back to the</p> <p>5 editorial that she wrote in connection --</p> <p>6 that Dr. Terry wrote in connection with the</p> <p>7 O'Brien (2024) paper.</p> <p>8 A. Yes.</p> <p>9 Q. Okay. It says "In the</p> <p>10 article that accompanies this editorial,"</p> <p>11 the third paragraph, "O'Brien et. al. use a</p> <p>12 variety of methods to address the impact of</p> <p>13 bias and misclassification on the</p> <p>14 association between intimate care products,</p> <p>15 (i.e. genital powder use and douching) and</p> <p>16 ovarian cancer in the Sister Study, a</p> <p>17 prospective cohort of U.S. women. These</p> <p>18 include quantitative bias analysis to</p> <p>19 examine different exposure reporting</p> <p>20 scenarios, as well as reclassifying</p> <p>21 exposures to address recall bias," correct?</p> <p>22 A. That is what it states.</p> <p>23 Q. Okay. And so the authors of</p> <p>24 this editorial, which accompanied the</p>	<p style="text-align: right;">Page 197</p> <p>1 potential risks. These are, like,</p> <p>2 very couched statements and, like,</p> <p>3 again, doesn't point to a reliable</p> <p>4 association between talc use and</p> <p>5 ovarian cancer.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Move to strike. That was not</p> <p>8 question.</p> <p>9 My question was, they</p> <p>10 acknowledge the methodology used to examine</p> <p>11 quantitative bias analysis and recall bias</p> <p>12 scenarios, it acknowledges that in the</p> <p>13 editorial, correct?</p> <p>14 A. Again, if you just mean by</p> <p>15 acknowledging if, we just mean that they</p> <p>16 paraphrase what was said in the O'Brien</p> <p>17 description in their paper of what they</p> <p>18 did, then, yes, they do paraphrase that.</p> <p>19 Q. All right. So we've gone</p> <p>20 through the peer review by JCO, the Journal</p> <p>21 of Clinical Oncology, the NIH document, the</p> <p>22 Harris editorial, the JSCO paper, you</p> <p>23 believe that all of these different levels</p> <p>24 of review that was done outside of</p>

<p style="text-align: right;">Page 198</p> <p>1 litigation did not do the kind of rigor 2 analysis that you did as a paid expert for 3 Johnson & Johnson, true? 4 A. I don't know why they didn't 5 dig into the analysis methods. I'm not 6 sitting here trying to ascribe motives or 7 anything. You know, as you see in my 8 report, I go into the details of what the 9 problems are. And I point to why they're 10 problems. And the clean analysis of the 11 paper, Table A2, clearly that prospective, 12 careful analysis, at least careful as far 13 as I can tell, is indicative of no. 14 Q. Okay. And other than paid 15 experts like yourself and Dr. Diette, 16 nobody else has expressed the opinion that 17 you have expressed hear, true? 18 A. I don't know -- 19 MS. LEHMAN: Object to form. 20 THE WITNESS: -- what other 21 people have expressed outside of 22 what I've read and heard. I don't 23 know of anybody that's -- but I do 24 know that there are experts out</p>	<p style="text-align: right;">Page 200</p> <p>1 BY MR. TISI: 2 Q. -- that you know of? 3 A. Okay. I mean, that was a 4 really long question and there was -- you 5 said, like, notoriety I think -- 6 Q. Let me rephrase -- 7 A. Notoriety is kind of a 8 negative -- 9 Q. Let me withdraw the question. 10 I will withdraw the question. Other than 11 you and Dr. Diette and maybe Dr. Merlo who 12 are paid experts by Johnson & Johnson, have 13 you seen any scientists come forward and 14 express any concerns with this paper in a 15 public forum? 16 MS. LEHMAN: Objection. Asked 17 and answered. 18 THE WITNESS: I mean, I 19 haven't, but I would be very 20 surprised on how they would be. 21 There's been -- the paper was 22 published May 20, it has been a 23 month and two weeks. You already 24 pointed out how the peer-review</p>
<p style="text-align: right;">Page 199</p> <p>1 there that would look at the 2 methods here and would determine 3 that they're clearly problematic, 4 because they are. It's just -- 5 BY MR. TISI: 6 Q. All right. So let me just -- 7 let me just break that down. And, 8 actually, I'm going to move to strike the 9 answer as nonresponsive. 10 My question is, it is now 11 mid July, this paper was published to great 12 notoriety in May, okay. It has been 13 reviewed and commented on by the NIH, JSCO, 14 an editorial that accompanied the paper and 15 all kind of those things, and I understand 16 you think they're just parroting what the 17 author says. I got it. 18 My question is, has anybody 19 that has not been paid by J&J put their 20 name on it, either a paper or a speech or a 21 publication which in any way criticized 22 this paper -- 23 MS. LEHMAN: Object to form. 24 Asked and answered.</p>	<p style="text-align: right;">Page 201</p> <p>1 process could take over a year, 2 so -- 3 BY MR. TISI: 4 Q. So the answer would be no? 5 MS. LEHMAN: Please let him 6 finish. 7 MR. TISI: He has not seen 8 any -- you have not seen anybody in 9 a speech, a commentary, a letter, 10 anywhere other than J&J's experts 11 that were paid to criticize this 12 paper; is that true or not true? 13 MS. LEHMAN: Objection. Asked 14 and answered. 15 BY MR. TISI: 16 Q. It is true, isn't it? 17 A. I have already said that I'm 18 not aware of anyone that's dug into this in 19 detail and picked up on the issues that 20 I've expressed. 21 Q. All right. So let's talk 22 about O'Brien. We want to get into the 23 methods, let's get into the methods. You 24 would agree that O'Brien (2024) --</p>

<p style="text-align: right;">Page 202</p> <p>1 A. Can I ask that if we're going 2 to be starting kind of a new section that 3 maybe we take a five-minute break? 4 MR. TISI: I have no problem 5 with that. Thank you. This is a 6 good time to do it. 7 THE WITNESS: Great. Thank 8 you. 9 MR. TISI: Five minutes, if 10 you don't mind. If you want to 11 take longer, that's fine with me as 12 well. 13 ----- 14 (A recess was taken at this time.) 15 ----- 16 BY MR. TISI: 17 Q. So I spent the time talking 18 about the peer-review process and multiple 19 levels of review and the authors 20 themselves, I really want to get into the 21 actual studies and your criticisms of them. 22 So let's kind of move to that. 23 First of all, I need to ask 24 you a couple of preliminary questions and</p>	<p style="text-align: right;">Page 204</p> <p>1 particular period of time, is related to 2 the risk of ovarian cancer. That's the 3 ultimate research question, right? 4 MS. LEHMAN: Object to form. 5 THE WITNESS: You know, when 6 you say -- 7 BY MR. TISI: 8 Q. You mention it in your 9 report, so let's talk about it. 10 A. Okay. 11 Q. On page 7 -- on paragraph 17 12 of your report, you say the goal is to 13 estimate the association between genital 14 talc use and ovarian cancer. That's the 15 ultimate goal, you want to know whether or 16 not there is an association between genital 17 talc use and ovarian cancer. That's the 18 ultimate point of all these studies, right? 19 A. Yeah, I don't want to go as 20 far as saying it's the ultimate point of 21 all these studies, but what I state here is 22 I think a reasonable interpretation of what 23 they were doing is that their goal was to 24 estimate the association between genital</p>
<p style="text-align: right;">Page 203</p> <p>1 hopefully that will frame what we're 2 talking about here. First of all, in your 3 litigation report, you discuss several 4 articles coming out of the Sister Study, 5 Gonzalez, O'Brien (2020), O'Brien (2023), 6 and O'Brien (2024), right? 7 A. Yes. 8 Q. Okay. And the general import 9 of all of these studies, if you kind of 10 take it to the mountaintop, is whether or 11 not genital talc use over a woman's 12 lifetime is associated with the risk of 13 ovarian cancer, true? 14 A. Yeah. I don't know that all 15 of the papers were thinking about over a 16 woman's life, but I think it's true they're 17 all concerned with the association of talc 18 use and ovarian cancer. 19 Q. Well, that's -- I mean, your 20 qualification kind of brings the important 21 question, what we really want to know from 22 a public health standpoint is whether or 23 not if a woman uses talcum powder over -- 24 at any point in her lifetime for any</p>	<p style="text-align: right;">Page 205</p> <p>1 talc use and ovarian cancer. 2 Q. Okay. And that's a worthy 3 goal, right? That's an important public 4 health issue, right? 5 MS. LEHMAN: Object to form. 6 THE WITNESS: Well -- 7 BY MR. TISI: 8 Q. It's a worthy research goal, 9 true? 10 A. Right. It's a question you 11 might want to ask from the data, but you 12 can't decouple from asking, like, is there 13 an effect of genital talc use and ovarian 14 cancer. So, it's, obviously, part of the 15 same bucket. 16 Q. But, ultimately, the idea of 17 science of this type is to figure out 18 whether or not a product, if used, is 19 capable of using a disease. That's what 20 epidemiology does, right? 21 A. Now you've jumped another 22 step and brought in the word "causation," 23 which is more than association, so -- 24 Q. Let's say association. Let</p>

<p style="text-align: right;">Page 206</p> <p>1 me rephrase the question. One of the goals 2 of epidemiology is to determine whether or 3 not the use of a substance is capable of -- 4 is associated with a disease, right? 5 Right? 6 A. But now you've reversed -- so 7 here, in the statement you've highlighted, 8 we're talking about estimation. 9 Q. I'm not talking about that. 10 Honestly, you need to answer my question -- 11 A. I am -- 12 Q. -- whether? 13 A. I am answering your question. 14 Q. No, I'm asking the question. 15 What are the goals of the epidemiology, I'm 16 not talking about this case, one of the 17 goals of epidemiology is to decide whether 18 or not a particular product or drug or 19 exposure is associated with a disease, 20 true? 21 A. It's one of many possible 22 epidemiology questions. 23 Q. Okay. And would you also 24 agree that an important question for this</p>	<p style="text-align: right;">Page 208</p> <p>1 down. I really can't. 2 THE WITNESS: I apologize. 3 BY MR. TISI: 4 Q. Would you agree that in 5 studying the question of whether there's an 6 association between talc and ovarian 7 cancer, the important question is whether 8 or not the person actually took or was 9 exposed to genital talc? 10 A. I don't think it's an 11 important -- it's not really a question of 12 this study. 13 Q. Okay. Do you think it's 14 important to have reliable -- if the 15 question is whether or not genital talc is 16 associated with ovarian cancer, do you 17 think that having questions that actually 18 ask that question is an important thing to 19 have? 20 A. I think that when you're 21 designing a study, you would try to ask 22 questions that ascertain what you're 23 interested in and, but it's just -- and you 24 want to try and collect that data in an</p>
<p style="text-align: right;">Page 207</p> <p>1 issue, for this case, talc and ovarian 2 cancer, is whether the women in the study 3 were actually and in fact ever in their 4 lifetime exposed to genital talc? 5 MS. LEHMAN: Object to form. 6 THE WITNESS: I don't think I 7 recall anywhere in the paper that 8 they say that's the goal of this 9 study. 10 BY MR. TISI: 11 Q. I didn't ask that question, 12 Doctor. Honestly, you need to listen to my 13 question. My question is, an important 14 question is whether or not women in the 15 Sister Study were actually and in fact in 16 their lifetime been exposed to genital 17 talc? 18 A. But you emphasized the 19 important question, if it's -- 20 Q. Just answer the exact -- 21 A. If it's not people in the 22 field -- 23 THE STENOGRAPHER: Wait a 24 minute. I can't take you both</p>	<p style="text-align: right;">Page 209</p> <p>1 unbiased way that avoids sort of, say, kind 2 of contamination of the data. 3 Q. Well, in the real world, 4 okay, what you really want to do in this 5 particular study, this particular research 6 question is whether or not women actually 7 were exposed to genital talc. You want to 8 know that answer, right? 9 A. Again, that's not a question 10 of the study. The study's question is 11 about estimating the association between 12 genital talc use and ovarian cancer. 13 Q. Right. And center to that is 14 whether or not women actually used genital 15 talc? 16 A. Whether or not women used 17 genital talc is the exposure variable that 18 you're looking at. 19 Q. Now, if you go to page 5 of 20 your report, you talk about what the 21 initial enrollment questionnaire asked, 22 true? 23 A. Correct. 24 Q. And the initial questionnaire</p>

<p style="text-align: right;">Page 210</p> <p>1 did not ask whether a study participant had 2 ever used genital talc, did it? 3 A. No, it didn't explicitly ask 4 that, no. 5 Q. Okay. In fact, the 6 investigators asked whether the women 7 actually used genital talc at two very 8 specific times, from 10 to 13 years old or 9 a year before enrollment, true? 10 MS. LEHMAN: Object to form. 11 THE WITNESS: The 12 questionnaire did ask about talcum 13 powder use between the ages of 10 14 to 13 and in the past 12 months. 15 BY MR. TISI: 16 Q. Now, if you go back to the 17 Gonzalez paper, you know that the average 18 range of enrollee was between 35 and 75 19 years old, correct? 20 A. Do you want me to go back to 21 that paper? I would have to check those 22 numbers. 23 Q. Sure. Let's do it. Gonzalez 24 was Exhibit No. 18. If you look at the</p>	<p style="text-align: right;">Page 212</p> <p>1 it, true? 2 A. I don't know which years they 3 were more likely to use it. 4 Q. Well, the Sister Study 5 investigators actually looked at that 6 question, didn't they? 7 A. You would have to remind me 8 where they do that. 9 Q. Okay. Well, let's talk about 10 that in a moment. You know that the NIH 11 studies and Sister Study investigators 12 found that the 20- to 50-year gap in 13 exposure created by the original enrollment 14 questionnaire created a problem when trying 15 to answer the actual research question and 16 that is whether or not genital talc use 17 during a woman's lifetime was associated 18 with ovarian cancer. And that is because 19 the original questionnaire did not capture 20 lifetime use, true? 21 A. I'm sorry, where are you 22 seeing this? 23 Q. Well, let's go to -- let's go 24 to the study, Exhibit No. 16.</p>
<p style="text-align: right;">Page 211</p> <p>1 methods section on page 2, see, enrollees 2 were aged between 75 -- 35 to 74 years old, 3 correct? 4 A. Yes, that's what it states. 5 Q. Okay. So using the Sister 6 Study enrollees, using the youngest of the 7 Sister Study enrollees, a 35-year-old 8 woman, the enrollment questionnaire did not 9 ask her about genital talc use between the 10 ages of 13 and 30 years old, a period of 20 11 years, correct? 12 A. It depends when -- I'm sorry, 13 because of the previous 12 months, that's 14 correct. 15 Q. Right. Okay. Using the 16 oldest Sister Study enrollee, a 74-year-old 17 woman, the enrollment questionnaire did not 18 ask her about her use between the age of 14 19 and 73, a period of 49 years, true? 20 A. Yes. 21 Q. Okay. Given the Sister Study 22 enrollment age range, the original Sister 23 Studies did not ask about talc use during 24 the years that they were more likely to use</p>	<p style="text-align: right;">Page 213</p> <p>1 A. Okay, yes. 2 Q. If you go to page 4, it says, 3 go to page 4, please. Okay. Slide down, 4 please. "Because the enrollment 5 questionnaire did not collect information 6 on use between age 14 and one year prior to 7 enrollment, it was possible for a 8 participant to report never use on the 9 enrollment questionnaire and ever use on 10 the follow-up questionnaire without 11 contradicting themselves;" is that true? 12 A. Yes, I don't disagree with 13 that statement. 14 Q. Okay. Now let's go back to 15 O'Brien (2024), Exhibit No. 8. On page 14. 16 Top left corner, they say "The intimate 17 care product questions were initially 18 limited to two specific time periods; age 19 10 to 13 and the last year, and did not 20 capture lifetime exposure or use during the 21 most likely exposure period of ages 20 to 22 39 years." 23 Do you see that? 24 A. Yes, I see that they say</p>

<p style="text-align: right;">Page 214</p> <p>1 that.</p> <p>2 Q. Okay. Well, they actually</p> <p>3 have evidence to support that, right?</p> <p>4 A. They cite their 2023 paper, I</p> <p>5 have no reason to dispute that, no.</p> <p>6 Q. Let's go back and look at it,</p> <p>7 okay?</p> <p>8 A. Okay.</p> <p>9 Q. Let's go back to the 2023</p> <p>10 study.</p> <p>11 A. Remind which --</p> <p>12 Q. First of all, just for the</p> <p>13 record, if you look at Exhibit No. 17,</p> <p>14 that's the supplemental questionnaire that</p> <p>15 was done that you have problems with,</p> <p>16 right?</p> <p>17 A. This is the -- this is a</p> <p>18 follow-up one?</p> <p>19 Q. Uh-huh. And the talc</p> <p>20 questions are not until number 138 there.</p> <p>21 A. Did you say number 38 in the</p> <p>22 questions?</p> <p>23 Q. It's 138 on page --</p> <p>24 actually --</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. Yes.</p> <p>2 A. I just want to make sure I'm</p> <p>3 completely following the path.</p> <p>4 Q. Go back to Exhibit No. 8 on</p> <p>5 page 14.</p> <p>6 A. Page 14.</p> <p>7 Q. Okay. They say the initial</p> <p>8 questionnaire, "the initial intimate care</p> <p>9 product questions were related to two</p> <p>10 specific time periods; ages 10 to 13 years</p> <p>11 and the last year, and did not capture</p> <p>12 lifetime exposure or use during the most</p> <p>13 likely exposure periods of 20 to 39 years."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And they cite their own study</p> <p>17 coming out of the Sister Study to</p> <p>18 demonstrate that, correct?</p> <p>19 A. They do cite their own study</p> <p>20 for that.</p> <p>21 Q. And let's go to Exhibit</p> <p>22 No. 16, which is their 2023 study.</p> <p>23 A. I'm there.</p> <p>24 Q. Okay. And if we go to the</p>
<p style="text-align: right;">Page 215</p> <p>1 A. I don't see the page numbers.</p> <p>2 Q. Yeah, I'm just going to ask</p> <p>3 you, this is the questionnaire that you</p> <p>4 reviewed, correct? I don't want to waste</p> <p>5 time on it.</p> <p>6 A. Without checking every page,</p> <p>7 I believe it looks like it's the same</p> <p>8 questionnaire, yes.</p> <p>9 -----</p> <p>10 (Sister Study Questionnaire</p> <p>11 marked Kornak Exhibit 17 for</p> <p>12 identification.)</p> <p>13 -----</p> <p>14 BY MR. TISI:</p> <p>15 Q. Okay. Now, going back to the</p> <p>16 question of the appropriateness of the</p> <p>17 original questionnaire to determine the</p> <p>18 ages where women were more likely to use</p> <p>19 talc and that original questionnaire</p> <p>20 missing those dates, they referred, the</p> <p>21 authors of O'Brien (2024) refer to their</p> <p>22 2023 study, correct?</p> <p>23 A. So can you remind me where</p> <p>24 that --</p>	<p style="text-align: right;">Page 217</p> <p>1 first page, it says, this actually they</p> <p>2 were using the follow-up questionnaire from</p> <p>3 2017 to 2019, right? It is up on the</p> <p>4 screen.</p> <p>5 A. Okay. That is what it</p> <p>6 states.</p> <p>7 Q. Okay. So they make a</p> <p>8 distinction between the one questionnaire</p> <p>9 which asks for a very specific time frame,</p> <p>10 a three-year period, and the follow-up</p> <p>11 questionnaire which talks about lifetime</p> <p>12 use, correct?</p> <p>13 A. They do make that distinction</p> <p>14 yes.</p> <p>15 Q. And this, again, the use of</p> <p>16 this questionnaire passed peer review as</p> <p>17 well, correct?</p> <p>18 A. I don't know whether the</p> <p>19 questionnaire was reviewed or not.</p> <p>20 Q. Okay. This is published in</p> <p>21 the Journal of --</p> <p>22 A. But I can say that I think</p> <p>23 it's, like, a bad design that they would</p> <p>24 have different questionnaires at enrollment</p>

<p style="text-align: right;">Page 218</p> <p>1 and haven't thought about what they really 2 want to ask and then recall bias is 3 introduced and they start introducing all 4 these other aspects and get all these 5 problems are, but -- 6 Q. So this is another journal 7 that got it wrong, the Journal of 8 Epidemiology, which said, you know, 9 approved a peer-reviewed literature that 10 compares the enrollment questionnaire and a 11 subsequent questionnaire in a cohort study? 12 A. I don't believe I said the 13 journal got anything wrong. I'm just 14 saying that I don't think they were good 15 designs. 16 Q. Okay. All right. Now, if 17 you go to O'Brien (2023), page 14, there's 18 a table, correct? 19 A. Yes. 20 Q. And on page -- have you seen, 21 had you looked at this table before? 22 A. Yeah, I've seen it. I didn't 23 look at it -- I don't believe I looked at 24 it in great detail.</p>	<p style="text-align: right;">Page 220</p> <p>1 used it their whole lifetime, then what 2 they said between 10 and 13 agrees exactly 3 with what they used in their whole 4 lifetime. There's no disagreement. This 5 6,438 that said they used it in the teens 6 could be the same, could be 6,438 of the 7 8,002 that used it in their twenties. We 8 have no idea -- 9 Q. The enrollment 10 questionnaire -- 11 A. There's no cross tables here 12 for us to know where they agree in 13 different periods or disagree. And I think 14 O'Brien makes the statement that there is 15 good agreement between -- in their 2023 16 paper, that there's good agreement between 17 the first survey and the later survey -- 18 Q. Honestly, I'm not even 19 understanding your answer. 20 A. I can slow it down if -- 21 Q. No, no, you don't need to 22 slow it down. My question is, did the 23 original questionnaire ask about use in 24 twenties and thirties?</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. Well, it talks about the vast 2 majority of the use were in the twenties 3 and thirties, correct? 4 A. I don't know that the table 5 talks about anything. It provides numbers. 6 Q. So it says self-reported, it 7 says "all." Okay. Use in the twenties, 8 8,002 people, use in the thirties, 6,416 9 people. Do you see it? 10 A. Yes. 11 Q. Now, if the earliest age of a 12 woman enrolling in this study was 35 years 13 old to 75 years old, the original study 14 design, the enrollment questionnaire would 15 have missed this time frame by necessity, 16 correct? 17 A. No. 18 Q. Tell me a circumstance under 19 which the -- a 35-year-old woman who 20 enrolled -- who answered your enrollment 21 questionnaire correctly would be answering 22 about talc use in the early twenties? 23 A. Well, if they said that, yes, 24 I used between ages 10 to 13 and then they</p>	<p style="text-align: right;">Page 221</p> <p>1 A. I think I already answered 2 that, that, no, it doesn't ask specifically 3 about use in twenties and thirties, but 4 that -- 5 Q. If a woman is 35 years old 6 and only used talc in her twenties, let's 7 say from age 21 to age 34, could she answer 8 the questions on the original questionnaire 9 no and no and still have been a talc user? 10 MS. LEHMAN: Object to form. 11 THE WITNESS: She could answer 12 no for the period 10 to 13 and for 13 the past 12 months and still have 14 been a talc user in her twenties, 15 for example, yes. 16 BY MR. TISI: 17 Q. Okay. Now, the data on the 18 supplemental questionnaire which was asked 19 was more comprehensive in terms of 20 capturing lifetime use, true? Whether you 21 think it was affected by recall bias or 22 not, it asks the question that was not 23 asked in the original survey, true? 24 A. Well, I think it depends on</p>

<p style="text-align: right;">Page 222</p> <p>1 what you exactly mean there, because, yes, 2 it asks about the specific intervals and I 3 already agreed with you it asks about these 4 intervals that are not asked about in the 5 first survey. But it gives women less 6 options into how to answer about each 7 interval. They're kind of forced into a 8 yes-or-no situation or to not answer. And 9 as such, the sort of the problems that are 10 incorporated far outweigh any potential 11 extra advantage of having the specific 12 intervals. 13 Q. Doctor, I'm going to move to 14 strike. That's not my question. 15 My question was, does the 16 questionnaire number two ask about time 17 frames beyond that of questionnaire number 18 one? 19 A. I've already answered your 20 question that there are specific intervals 21 in here -- 22 Q. So -- 23 MS. LEHMAN: Hold on. Hold 24 on. Let him finish.</p>	<p style="text-align: right;">Page 224</p> <p>1 they used it in their teens. So 2 there is no evidence to say that 3 there's suddenly these big 4 differences in who used it in 5 their twenties versus who used it 6 in their teens and I think 7 O'Brien says that. 8 BY MR. TISI: 9 Q. Well, O'Brien actually -- 10 move to strike your answer, which is, 11 again, nonresponsive -- 12 A. I did respond, again, to your 13 question, again. Again -- 14 Q. But O'Brien -- 15 A. The interval -- 16 - - - - - 17 (Simultaneous crosstalk.) 18 - - - - - 19 BY MR. TISI: 20 Q. Doctor, I move to strike. 21 Let's move on. 22 The statement that O'Brien 23 makes, the intimate care product questions 24 were related to two time frames, the</p>
<p style="text-align: right;">Page 223</p> <p>1 THE WITNESS: -- for use in 2 the twenties and thirties that were 3 not explicitly asked in the first 4 questionnaire. But at the same 5 time, the way these questions are 6 asked gives women less options and 7 it led to differential recall 8 bias -- sorry, differential bias as 9 can be seen by the proportion of 10 cases that didn't answer compared 11 to the proportion of controls that 12 didn't answer. And that's really 13 going to outweigh any of, like, 14 what little advantage you might 15 gain by looking at extra intervals. 16 And I should say, even if 17 you look at these numbers here, 18 we're talking about pretty 19 consistent numbers across each 20 period. And so it could just be 21 that this is essentially mostly 22 the same group of people that's 23 saying they used in each period, 24 which means they would have said</p>	<p style="text-align: right;">Page 225</p> <p>1 original enroll questionnaire, ages 10 to 2 13 and the last year, and did not capture 3 lifetime exposure or use during the most 4 likely exposure period of ages 20 to 30 5 years. Are they right or are they wrong? 6 MS. LEHMAN: Object to form. 7 THE WITNESS: To be honest, I 8 don't know for sure that they're 9 right or wrong, but if those, for 10 example, here those 6,438 that said 11 they used it in their teens, 12 although this is problematic 13 because it is from the second -- 14 the follow-up survey, but if you 15 accepted that, then those 6,438 16 could be the same 6,416 that used 17 in their thirties, they could be 18 the same within those that used it 19 in their twenties. So it would be 20 actually just asking if that's the 21 case that -- and O'Brien seems to 22 imply that it is in 2023, then that 23 would be the same set all the way 24 through.</p>

<p style="text-align: right;">Page 226</p> <p>1 So if you're asking about</p> <p>2 one period, then the implication</p> <p>3 is that they're very likely to</p> <p>4 have used through the whole</p> <p>5 period. So, yeah, the answer</p> <p>6 is --</p> <p>7 BY MR. TISI:</p> <p>8 Q. You're guessing, aren't you?</p> <p>9 I mean, you are guessing, aren't you?</p> <p>10 MS. LEHMAN: Object to form.</p> <p>11 THE WITNESS: I would say that</p> <p>12 it's not my responsibility -- when</p> <p>13 I look at a paper and I'm reviewing</p> <p>14 it, I want them to demonstrate to</p> <p>15 me that there's a problem. They</p> <p>16 should have given all the</p> <p>17 information to be able to do that,</p> <p>18 but I'm not --</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay.</p> <p>21 A. -- convinced because</p> <p>22 O'Brien says so.</p> <p>23 Q. So O'Brien (2023), if you go</p> <p>24 to page 6, at the very top, it says "As</p>	<p style="text-align: right;">Page 228</p> <p>1 within collection of supplemental data</p> <p>2 which was trying to address the question of</p> <p>3 whether or not the women had lifetime use,</p> <p>4 correct?</p> <p>5 A. That's kind of my impression</p> <p>6 of the extension of the questions, that</p> <p>7 they wanted to look at that.</p> <p>8 Q. Right.</p> <p>9 A. And my impression was that</p> <p>10 their conclusions were that the perspective</p> <p>11 baseline data were quite reliably</p> <p>12 representative of the lifetime use.</p> <p>13 Q. Right. And, of course,</p> <p>14 asking in a supplemental questionnaire</p> <p>15 would raise two questions, first, would be</p> <p>16 what do you do with this contradictory data</p> <p>17 or potentially contradictory data and what</p> <p>18 do you do, for example, if a woman dies and</p> <p>19 can't fill out the supplemental</p> <p>20 questionnaire, correct?</p> <p>21 A. I think those are important</p> <p>22 questions to consider, yes.</p> <p>23 Q. Okay. And the authors in the</p> <p>24 O'Brien (2024) addressed this data</p>
<p style="text-align: right;">Page 227</p> <p>1 with douching, genital talc use was most</p> <p>2 common during ages 20 to 29," and then it</p> <p>3 goes on to say "Average age at first use</p> <p>4 was 21 years old, and while most women only</p> <p>5 used prior to menopause, a 32 percent use</p> <p>6 using before and after menopause."</p> <p>7 Do you see that?</p> <p>8 A. Yes, I see that.</p> <p>9 Q. Okay. And so what they're</p> <p>10 doing here is they're saying that when they</p> <p>11 actually look at the use between the first</p> <p>12 and second questionnaire, the first</p> <p>13 questionnaire didn't capture large periods</p> <p>14 of time, true?</p> <p>15 A. Again, I'm sort of going back</p> <p>16 and reviewing myself, but I agree with you</p> <p>17 that they didn't explicitly ask about those</p> <p>18 intervals, but that does not mean that it</p> <p>19 did not capture their usage across lifetime</p> <p>20 by just asking about a snapshot. I'm not</p> <p>21 saying that that's a good design. I think</p> <p>22 the design is flawed on multiple levels.</p> <p>23 Q. Well, you know, I assume that</p> <p>24 you agree that there are potential problems</p>	<p style="text-align: right;">Page 229</p> <p>1 contradiction and missing data with what</p> <p>2 the authors called a quantitative bias</p> <p>3 analysis, which although you disagree with</p> <p>4 it, are described in the paper, true?</p> <p>5 A. I disagree that it's really</p> <p>6 an analysis. I think it's just an</p> <p>7 imaginary what-if game.</p> <p>8 Q. Okay. But they describe</p> <p>9 their what-if game in the methods section</p> <p>10 of the paper, true?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And the methods that</p> <p>13 they use for analyzing the data from the</p> <p>14 enrollment and supplemental questionnaire,</p> <p>15 the contradictory data question, and the</p> <p>16 missing data imputation are disclosed and</p> <p>17 passed peer review, true?</p> <p>18 A. Well, they do say that the</p> <p>19 correction process, that the flipping of</p> <p>20 status, they do describe that and they</p> <p>21 do --</p> <p>22 Q. They describe --</p> <p>23 A. My brain is --</p> <p>24 Q. -- multiple --</p>

<p style="text-align: right;">Page 230</p> <p>1 A. I missed part of the</p> <p>2 question. Can you repeat the whole</p> <p>3 question again.</p> <p>4 Q. Sure. If you go to page 4 of</p> <p>5 Exhibit No. 8, which is the O'Brien (2024)</p> <p>6 article in the methods section, they</p> <p>7 describe a quantitative bias analysis.</p> <p>8 They described how they deal with</p> <p>9 contradictory data and how they deal with</p> <p>10 missing data, correct?</p> <p>11 A. On page 4, did you say?</p> <p>12 Q. Page 4. Under quantitative</p> <p>13 bias analysis.</p> <p>14 A. Okay. Yes.</p> <p>15 Q. Okay. And that description</p> <p>16 passed peer review, true?</p> <p>17 A. No, the paper passed peer</p> <p>18 review and was published. Whether they</p> <p>19 focused in on that section or not, I don't</p> <p>20 know.</p> <p>21 Q. Okay. And they put their</p> <p>22 results of their methods on a chart on</p> <p>23 page 7, Table 2 of the article, correct,</p> <p>24 under quantitative bias analysis?</p>	<p style="text-align: right;">Page 232</p> <p>1 would not say it's all transparent</p> <p>2 for everybody to see, because they</p> <p>3 don't explain that.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Well, but there is a section</p> <p>6 in the paper where they say they're a</p> <p>7 corresponding author, if you have any</p> <p>8 questions, here's my email address, email</p> <p>9 me, right?</p> <p>10 MS. LEHMAN: Object to form.</p> <p>11 Asked and answered.</p> <p>12 BY MR. TISI:</p> <p>13 Q. And you didn't do that, true?</p> <p>14 A. I've already explained why I</p> <p>15 didn't do it, because I didn't --</p> <p>16 Q. Okay.</p> <p>17 A. But when you write a paper,</p> <p>18 it's accepted academic practice that you</p> <p>19 describe the methods and you justify your</p> <p>20 methods. You don't just say, oh, email me</p> <p>21 afterwards in case you don't know --</p> <p>22 Q. They did describe their</p> <p>23 methods. You just don't think they did it</p> <p>24 well enough for you, right? They described</p>
<p style="text-align: right;">Page 231</p> <p>1 A. Yes, they put their results</p> <p>2 there for their four different scenarios.</p> <p>3 Q. For all the world to see,</p> <p>4 they weren't hiding anything, right?</p> <p>5 MS. LEHMAN: Object to form.</p> <p>6 THE WITNESS: Oh, well, I</p> <p>7 wouldn't -- I don't know -- okay,</p> <p>8 so the word "hiding" might be a</p> <p>9 mischaracterization. I don't want</p> <p>10 to say that they are, again, I</p> <p>11 don't want to ascribe motives to</p> <p>12 what is missing from the paper or</p> <p>13 not missing. But they certainly</p> <p>14 don't, for example, say why they</p> <p>15 chose the 80 percent and 90 percent</p> <p>16 for correction levels. I mean,</p> <p>17 they don't talk about how they got</p> <p>18 to those numbers, whether they did</p> <p>19 some separate analyses, whether</p> <p>20 they followed up with patients to</p> <p>21 try to ascertain what those</p> <p>22 proportions should ideally be.</p> <p>23 They just pulled them out of thin</p> <p>24 air, as far as I could tell. So I</p>	<p style="text-align: right;">Page 233</p> <p>1 it, on page 4, they described the</p> <p>2 quantitative bias analysis, correct?</p> <p>3 A. Well, again --</p> <p>4 MS. LEHMAN: Object to form.</p> <p>5 THE WITNESS: I don't think</p> <p>6 that this is kind of any kind of</p> <p>7 analysis, they just chose a</p> <p>8 proportion and flipped it.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Okay. And they --</p> <p>11 A. It's an equation. It's not</p> <p>12 an analysis.</p> <p>13 Q. And they found correcting for</p> <p>14 missing and contradictory analysis, the</p> <p>15 hazard ratio was 1.82, meaning a</p> <p>16 statistically significant increase of</p> <p>17 82 percent of ovarian cancer with genital</p> <p>18 powder use, true?</p> <p>19 A. I'm sorry, where are you?</p> <p>20 Q. Four, at the bottom, ever</p> <p>21 use, ovarian cancer.</p> <p>22 A. That's not true. That also</p> <p>23 involves more than just their correction</p> <p>24 for contradictory data. That involves</p>

<p style="text-align: right;">Page 234</p> <p>1 their multiple imputation --</p> <p>2 Q. I said that.</p> <p>3 A. I'm sorry.</p> <p>4 Q. You didn't hear my question.</p> <p>5 Let me read it again. Okay.</p> <p>6 And they found after they</p> <p>7 corrected for missing and contradictory</p> <p>8 data that the hazard ratio was 1.82,</p> <p>9 meaning a statistically significant</p> <p>10 82 percent increased risk of ovarian cancer</p> <p>11 with genital powder use?</p> <p>12 A. I object to the term that</p> <p>13 they corrected it. I don't think this is a</p> <p>14 correction. I think this is arbitrary</p> <p>15 manipulation.</p> <p>16 Q. I'm not asking if you agree,</p> <p>17 I'm asking you that's what they reported,</p> <p>18 right?</p> <p>19 A. They report for their</p> <p>20 Scenario 4, whatever you want to call it,</p> <p>21 that the point estimate that they get for</p> <p>22 ever use hazard ratio is 1.82 with a</p> <p>23 confidence interval ranging from 1.36 to</p> <p>24 2.43 and they acknowledge that that</p>	<p style="text-align: right;">Page 236</p> <p>1 Q. And then they said women who</p> <p>2 used it in their twenties, the risk was</p> <p>3 1.88, statistically significant, correct?</p> <p>4 A. Okay. Again, with the same</p> <p>5 caveats, after during their manipulation</p> <p>6 and multiple imputation, that's correct.</p> <p>7 Q. And when they used it in</p> <p>8 their thirties, it was 2.08, correct?</p> <p>9 A. That there was their estimate</p> <p>10 with their correction and imputation</p> <p>11 processes.</p> <p>12 Q. Now. You're not aware of any</p> <p>13 scientist, other than those hired by</p> <p>14 Johnson & Johnson, who have said that these</p> <p>15 results reached by these NIH scientists and</p> <p>16 appear in this peer-reviewed paper were</p> <p>17 scientifically unreliable, true?</p> <p>18 MS. LEHMAN: Object to form.</p> <p>19 Asked and answered.</p> <p>20 THE WITNESS: I don't know</p> <p>21 that anybody has commented on these</p> <p>22 specific hazard ratios area in any</p> <p>23 way at all.</p> <p>24</p>
<p style="text-align: right;">Page 235</p> <p>1 contains recall bias.</p> <p>2 Q. Okay. Which, of course, they</p> <p>3 deal with in the paper, right?</p> <p>4 A. No, they don't deal with</p> <p>5 it --</p> <p>6 Q. Okay.</p> <p>7 A. -- adequately.</p> <p>8 Q. And they also concluded that</p> <p>9 women who used it more frequently for</p> <p>10 greater than two decades, and people who</p> <p>11 used it in their thirties, there was a</p> <p>12 statistically significant increased risk of</p> <p>13 greater than 2, meaning over 100 percent</p> <p>14 increased risk, true?</p> <p>15 A. I'm sorry, can you -- which</p> <p>16 one, what are we looking at here?</p> <p>17 Q. Look at table 3 on page -- on</p> <p>18 page 10, the long-term use greater than two</p> <p>19 decades for ovarian cancer, they have a</p> <p>20 risk of 2.01 with a confidence interval of</p> <p>21 1.39 to 2.91, correct?</p> <p>22 A. Yes, they have that estimate</p> <p>23 incorporating their contradictory process</p> <p>24 and there multiple imputation.</p>	<p style="text-align: right;">Page 237</p> <p>1 BY MR. TISI:</p> <p>2 Q. Okay. Now, let's talk about</p> <p>3 recall bias, one of the things that the</p> <p>4 authors were concerned about was the</p> <p>5 possibility, in fact, just the possibility</p> <p>6 of that some women who were given a</p> <p>7 supplemental questionnaire might</p> <p>8 differentially recall talc as compared to</p> <p>9 women who were not diagnosed with cancer.</p> <p>10 It might be the explanation for the 80 to</p> <p>11 100 percent increased risk in ovarian</p> <p>12 cancer in the Sister Study, true?</p> <p>13 MS. LEHMAN: Object to form.</p> <p>14 THE WITNESS: I think there's</p> <p>15 quite a bit to unpack in your --</p> <p>16 BY MR. TISI:</p> <p>17 Q. Then I'll rephrase the</p> <p>18 question. They were concerned about the</p> <p>19 potential that these hazard ratios might be</p> <p>20 affected by recall bias, true?</p> <p>21 A. Well, I think they've</p> <p>22 actually previously in papers made the</p> <p>23 statement that there is recall bias.</p> <p>24 Q. And they actually took that</p>

<p style="text-align: right;">Page 238</p> <p>1 into account, didn't they?</p> <p>2 A. They did some manipulations</p> <p>3 where they looked at a few scenarios where</p> <p>4 they did more flipping of data and they</p> <p>5 actually get sort of inconsistent.</p> <p>6 Q. Well, didn't the authors --</p> <p>7 A. But they're already starting</p> <p>8 from this problematic area where they've</p> <p>9 corrected their data in this arbitrary,</p> <p>10 manipulative fashion that leads you towards</p> <p>11 more recall bias. They add even more in</p> <p>12 through the missing imputation approach --</p> <p>13 Q. Got it --</p> <p>14 A. They do a little bit of that</p> <p>15 and they just don't do enough to not quite</p> <p>16 get them to be uncertain again. But it's</p> <p>17 really clear that it is uncertain.</p> <p>18 Q. Doctor, I mean, they have --</p> <p>19 this isn't the only time they looked at the</p> <p>20 potential for recall bias, they did it in</p> <p>21 the 2023 article, correct?</p> <p>22 A. I think they discussed recall</p> <p>23 bias in their 2023 article --</p> <p>24 Q. In fact, they --</p>	<p style="text-align: right;">Page 240</p> <p>1 because we all agree that -- before I get</p> <p>2 there, the potential for recall bias is</p> <p>3 just a potential, it's a theoretic concern,</p> <p>4 correct?</p> <p>5 A. No, recall bias is a real</p> <p>6 kind of bias.</p> <p>7 Q. Well, how much -- well, it's</p> <p>8 a real kind of bias, but whether it</p> <p>9 actually exists in a particular study is</p> <p>10 always a question of you have to</p> <p>11 acknowledge, but it's a theoretic concern,</p> <p>12 correct?</p> <p>13 MS. LEHMAN: Object to form.</p> <p>14 THE WITNESS: It's not</p> <p>15 theoretic. You acknowledge it,</p> <p>16 because it can be there.</p> <p>17 BY MR. TISI:</p> <p>18 Q. It can be there, there's no</p> <p>19 proof that it's there, it can be there,</p> <p>20 right?</p> <p>21 A. But when you are trying to</p> <p>22 demonstrate -- to determine that there is</p> <p>23 an association, you are not -- the onus is</p> <p>24 not on proving that it's there, the onus is</p>
<p style="text-align: right;">Page 239</p> <p>1 -----</p> <p>2 (Simultaneous crosstalk.)</p> <p>3 -----</p> <p>4 THE STENOGRAPHER: I'm not</p> <p>5 getting this, because you're</p> <p>6 talking over each other and Zoom</p> <p>7 just cuts it out. I don't even</p> <p>8 hear it.</p> <p>9 BY MR. TISI:</p> <p>10 Q. I'm sorry. Repeat yourself,</p> <p>11 Dr. Kornak.</p> <p>12 A. I don't remember exactly what</p> <p>13 I said.</p> <p>14 Q. In fact, let me -- in fact,</p> <p>15 they concluded that there wasn't much</p> <p>16 evidence for recall bias, even using the</p> <p>17 supplemental questionnaire, true?</p> <p>18 A. Where do you see that</p> <p>19 conclusion?</p> <p>20 Q. Well, let's look at it.</p> <p>21 A. Yeah, but let's look at it.</p> <p>22 I'm happy to look at it.</p> <p>23 Q. Let's look at page 13 of the</p> <p>24 douching study, back in 2023, exhibit --</p>	<p style="text-align: right;">Page 241</p> <p>1 on you to prove it's not there and it's</p> <p>2 reliable --</p> <p>3 Q. Perfect. Let's talk about</p> <p>4 that, because the authors do that, don't</p> <p>5 they?</p> <p>6 A. They proved they have recall</p> <p>7 bias? No, they don't do that.</p> <p>8 Q. Go to the douching study. It</p> <p>9 finds that recall of general -- page 6.</p> <p>10 A. Sorry, you're going to have</p> <p>11 to take me to -- what's the --</p> <p>12 Q. Let's go to Exhibit No. 16 --</p> <p>13 A. Yup.</p> <p>14 Q. -- on page 6. Well, first of</p> <p>15 all, let's start at the beginning. It says</p> <p>16 the conclusion of this study was that</p> <p>17 classification of -- and this is using both</p> <p>18 the recall, the follow-up question, and the</p> <p>19 initial questionnaire. Do you see that in</p> <p>20 the methods section, correct?</p> <p>21 A. Okay. So it's --</p> <p>22 Q. In the methods section --</p> <p>23 A. Where do you see want me to</p> <p>24 look first?</p>

<p style="text-align: right;">Page 242</p> <p>1 Q. In the methods section, they</p> <p>2 actually acknowledge both the initial</p> <p>3 questionnaire and the supplemental</p> <p>4 questionnaire, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And in their</p> <p>7 conclusion, they say "Classification of</p> <p>8 ever use in feminine hygiene products may</p> <p>9 be recalled with good consistency."</p> <p>10 Do you see that?</p> <p>11 A. Okay.</p> <p>12 Q. All right. And they actually</p> <p>13 go back and they actually analyze that</p> <p>14 question. If you go to page 6, they say</p> <p>15 "87 percent," on the fourth paragraph down,</p> <p>16 "recall of genital talc use was slightly</p> <p>17 less consistent than douching with</p> <p>18 87 percent of the women providing the same</p> <p>19 response at follow-up as they did</p> <p>20 enrollment."</p> <p>21 A. You say fourth paragraph</p> <p>22 down?</p> <p>23 Q. Yes. Starting with "recall,"</p> <p>24 it's on, recall of genital talc use was</p>	<p style="text-align: right;">Page 244</p> <p>1 (2024) study in order to make -- go from a</p> <p>2 risk to a no risk?</p> <p>3 A. Well, okay. So, first of</p> <p>4 all -- well, from a risk to a no -- from</p> <p>5 what risk to what no risk, that's --</p> <p>6 Q. Actually, let me withdraw</p> <p>7 that question, but this isn't the only time</p> <p>8 they looked at only prospective data in</p> <p>9 order to see whether or not there's a</p> <p>10 potential recall bias, true?</p> <p>11 A. I don't know that, but there</p> <p>12 was a lot of earlier questions, I don't</p> <p>13 know if you wanted them answered or don't</p> <p>14 want them answered. You bounced around a</p> <p>15 little bit.</p> <p>16 Q. Let me withdraw the question.</p> <p>17 You would agree with me that the results of</p> <p>18 the 23 study when they used both</p> <p>19 questionnaires, they found that almost</p> <p>20 90 percent of the women answered the</p> <p>21 question consistently, whether or not it</p> <p>22 was prospective or retrospective, true?</p> <p>23 A. I would have to remind myself</p> <p>24 with that, so what question specifically</p>
<p style="text-align: right;">Page 243</p> <p>1 slightly less consistent when comparing it</p> <p>2 to douching, okay, with 87 percent of the</p> <p>3 women providing the same response in</p> <p>4 follow-up as they did in enrollment,</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And so what they're</p> <p>8 saying is at least when they compare</p> <p>9 87 percent of the people provided the</p> <p>10 exact -- provided totally consistent</p> <p>11 answers, correct, recall bias didn't really</p> <p>12 effect in almost 90 percent of the women,</p> <p>13 true?</p> <p>14 MS. LEHMAN: Object to form.</p> <p>15 THE WITNESS: Well, if</p> <p>16 13 percent of the women were wrong</p> <p>17 and then got different answers that</p> <p>18 can have a substantial effect on</p> <p>19 recall bias.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Right, and what percentage,</p> <p>22 what is the tipping point that you have</p> <p>23 that -- of the amount of recall bias that</p> <p>24 would have to be introduced to the O'Brien</p>	<p style="text-align: right;">Page 245</p> <p>1 are they being consistent with or less</p> <p>2 consistent with? Because I'm not sure what</p> <p>3 question you could actually use from the</p> <p>4 first questionnaire and the second</p> <p>5 questionnaire that would allow you to</p> <p>6 answer this question precisely.</p> <p>7 Q. Well, doctor, you reviewed</p> <p>8 this --</p> <p>9 A. Let me finish, the role of</p> <p>10 the design that they have in the first</p> <p>11 questionnaire versus the second, there are</p> <p>12 no intervals that match. So how can you</p> <p>13 even assess this accurately? I don't get</p> <p>14 it.</p> <p>15 Q. Well, you read the paper and</p> <p>16 it was peer reviewed. I mean, I don't know</p> <p>17 what else to do, Doctor, other than redoing</p> <p>18 the entire study for you. You read the</p> <p>19 paper. They're reporting that there's a</p> <p>20 consistent --</p> <p>21 A. My focus was -- I looked at</p> <p>22 this paper, I'm not claiming I read this</p> <p>23 paper from first word to last word.</p> <p>24 Q. Okay. Well, let's look --</p>

<p style="text-align: right;">Page 246</p> <p>1 A. But what I am stating is, 2 what I did look at most carefully was 3 O'Brien (2024). But I am sort of like -- I 4 can't help but ask the scientific question 5 of what question were you determining 6 whether it's less -- was consistent or not? 7 Because in the first, you've already told 8 me that, again, that in the first 9 questionnaire, they had 10 to 13 and the 10 last 12 months. Well, where in the second 11 questionnaire, can you find the matching 12 questions to match the first? 13 Also, in the second 14 questionnaire, you don't even get the same 15 options for each question. So I don't see 16 how you check that. I don't see -- 17 Q. Well, you said that they did. 18 You said they did -- 19 MS. LEHMAN: Object to form. 20 THE WITNESS: I said they said 21 they did. I didn't say they did. 22 BY MR. TISI: 23 Q. All right. Doctor, you're 24 the expert here, I'm not. So let me ask</p>	<p style="text-align: right;">Page 248</p> <p>1 sometimes a little slow back and forth. 2 Q. I'm not critical. I'm not 3 critical. It says "We found that women 4 could recall whether they ever used 5 feminine hygiene products with good 6 consistency," and they were comparing both 7 questionnaires, right? 8 A. Yeah, I agree that's what 9 they said. 10 Q. All right. But that's not 11 only the time they ever looked at that 12 question, right, they looked at it in 13 O'Brien (2024), right? 14 A. In O'Brien -- okay, I might 15 want you to point to where, I'm not totally 16 sure which piece of O'Brien (2024) you're 17 referring to. O'Brien (2024) is that there 18 is differential recall. I mean, that's -- 19 Q. Well, except they looked at 20 the subgroup of people who only asked the 21 question prospectively, true, which would 22 have been fully prospective data? 23 A. Right, yeah, so that is the 24 Table A2. That's the one with the</p>
<p style="text-align: right;">Page 247</p> <p>1 you this question. Let's go to page 9 of 2 the douching study. 3 A. So which one? 4 Q. Page 9 of the douching study, 5 Exhibit 16. 6 A. So we're still on -- okay. 7 Q. And comparing both the 8 questionnaires, it says "We found that 9 women could recall whether they ever used 10 certain feminine products with good 11 consistency? 12 Do you see that? 13 A. Where? 14 Q. Third line down. 15 A. I'm looking at the wrong page 16 again, apologies. 17 Q. Thank you. Look at the 18 screen, it might be easier. 19 A. Like I said earlier, I think 20 I'm more comfortable reading the paper. 21 Q. That's okay. I'm just saying 22 it might be easier to find out where we 23 are. 24 A. Yes, sometimes, I guess I'm</p>	<p style="text-align: right;">Page 249</p> <p>1 result -- 2 Q. Well, let's see what they say 3 in Table A2. Look at page 12 of the study 4 and then we'll look at Table A2. 5 A. So page 12 of the paper. 6 Okay. I'm there. 7 Q. They say, on the very bottom 8 of the left-hand side of the column it says 9 "ever genital talc use --" 10 A. I thought, again, I'm 11 getting, I thought maybe you were pointing 12 to -- I thought you were talking about 13 O'Brien (2024). 14 Q. I am. On page 12 -- 15 A. On the screen, I'm seeing 16 what -- that doesn't look like -- 17 Q. Slide down, please. 18 A. Now I see O'Brien (2024). 19 Q. Okay. You need to follow me, 20 Doctor, just hold on a second. Go to 21 page 12. 22 A. Yes. 23 Q. Okay. If you slide down and 24 slide down, please, Jeff, it says the last</p>

<p style="text-align: right;">Page 250</p> <p>1 sentence on the left-hand side, "ever 2 genital talc use was positively associated 3 with ovarian cancer as a ratio of 1.82 but 4 showed no evidence of association pre- or 5 postmenopausal breast cancer or uterine 6 cancer," correct? 7 A. That is what is stated there, 8 yes. 9 Q. Now, if you go to Table A2, 10 the last -- you want to focus on the first 11 column. I'm going to focus on the last 12 column. 13 A. Okay. Sorry. 14 Q. Go to page A2 -- it's on 15 page -- Jeff, it's on page -- let's see 16 what page it is. It's I think the last -- 17 the third page from the end. Go to A2, 18 that's A1, Jeff. Okay. Now, Table 3, 19 Table A2, defined by exposure status 20 reported on fourth detailed follow-up and 21 use before then and incident cases 22 occurring after the time, fully 23 prospective. Do you see that? 24 A. Yeah, yeah.</p>	<p style="text-align: right;">Page 252</p> <p>1 THE WITNESS: No, that's not 2 fully my position, but sorry to 3 interrupt. 4 BY MR. TISI: 5 Q. Well, it does say the fully 6 prospective data you have for ovarian 7 cancer of 1.84, though not statistically 8 significant, increased risk in that 9 subgroup of people, correct? There's a 10 positive association, true? 11 A. Well, there's, you already 12 pointed to part of it, it's not 13 statistically significant. It's based on a 14 very small effective sample size here. 15 We're talking about 29 ovarian cancer cases 16 in that part of the study. That's a tiny 17 sample that, like, even statistics 101 will 18 tell you is very, very small. 19 Furthermore, I think there 20 is potential for recall bias here, because 21 now this part, not in the same sense of -- 22 it's almost like a bias by indication as 23 well here in that if you -- by this time 24 people were aware of the media stories,</p>
<p style="text-align: right;">Page 251</p> <p>1 Q. That means in the first 2 questionnaire, taking all people and on the 3 second questionnaire, only those people who 4 developed ovarian cancer after the 5 questionnaire, right? 6 A. Correct. 7 Q. Right. So it's fully 8 prospective, no recall bias, right? 9 A. Oh, no, you can't guarantee 10 there's no recall bias there. 11 Q. I'm not asking for a 12 guarantee -- 13 A. I agree, it's prospective, 14 but you said no recall bias, right -- 15 Q. Fully prospective -- 16 A. I don't think you can 17 guarantee a lack of recall bias. 18 Q. I'm not looking for 19 guarantees, Doctor. Okay? I'm looking at 20 fully -- your position is fully prospective 21 question -- fully prospective questions 22 have indicia of reliability because they do 23 not introduce recall bias, correct? 24 MS. LEHMAN: Object to form.</p>	<p style="text-align: right;">Page 253</p> <p>1 even though they were entering into a 2 prospective study, the only way, at the 3 beginning, we just know whether they're 4 ovarian cancer cases or not, but we don't 5 know if they have been discussing with 6 their medical doctor whether or not they 7 may be susceptible to ovarian cancer, 8 whether they're at high risk, whether they 9 may have had symptoms but were not fully 10 diagnosed -- 11 Q. You're guessing? 12 A. Sir? 13 Q. You're guessing, aren't you, 14 you don't know -- 15 A. My point is it's a 16 susceptibility to a bias that exists -- 17 Q. As is the fully 18 prospective -- 19 A. I wouldn't categorize it as 20 guessing. 21 - - - - 22 (Stenographer clarification.) 23 - - - - 24</p>

<p style="text-align: right;">Page 254</p> <p>1 BY MR. TISI:</p> <p>2 Q. Let's kind of back up for a</p> <p>3 second. You said that the number of</p> <p>4 participants exposed was a small sample</p> <p>5 size, correct, 31?</p> <p>6 A. I'm saying that the number of</p> <p>7 cases, so when you're working with a study,</p> <p>8 like, in where you're looking at cases</p> <p>9 versus non-cases, whether that it's in</p> <p>10 survival analysis or whether that's in</p> <p>11 logistic regression, the effective sample</p> <p>12 size you have is the bigger of the two</p> <p>13 groups, the cases versus the non-cases.</p> <p>14 Q. That wasn't --</p> <p>15 A. Twenty-nine cases, that's a</p> <p>16 very small number. It's reflected by the</p> <p>17 sheer width of the confidence interval.</p> <p>18 Q. Exactly. Exactly.</p> <p>19 A. Yes.</p> <p>20 Q. Gotcha. Okay. We'll looking</p> <p>21 for evidence of recall bias. Okay. Right?</p> <p>22 You have O'Brien (2023) which says --</p> <p>23 A. I'm sorry, you're going to</p> <p>24 have to explain how we were looking at</p>	<p style="text-align: right;">Page 256</p> <p>1 amount of the cases, because they are</p> <p>2 driving results.</p> <p>3 Q. Doctor, this isn't, honestly,</p> <p>4 you're not supposed to be an advocate,</p> <p>5 you're supposed to look at the data</p> <p>6 independently, right?</p> <p>7 MS. LEHMAN: Object to form.</p> <p>8 Argumentative.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Right?</p> <p>11 A. I agree, I'm talking --</p> <p>12 Q. Okay.</p> <p>13 A. All I'm doing is</p> <p>14 restating what --</p> <p>15 Q. Well, you're arguing with me.</p> <p>16 A. -- what the review was in my</p> <p>17 report and --</p> <p>18 Q. Well, you're arguing with me.</p> <p>19 In the 2023 article, they reported that</p> <p>20 there was evidence that the answer about</p> <p>21 talc use in the second questionnaire was</p> <p>22 consistent 90 percent of the time with</p> <p>23 people who reported on the first</p> <p>24 questionnaire, right, 87 percent of the</p>
<p style="text-align: right;">Page 255</p> <p>1 evidence of recall bias in O'Brien (2024).</p> <p>2 Q. Well, you're saying that only</p> <p>3 the prospective data, okay, does not carry</p> <p>4 the potential risk, and you can't even</p> <p>5 guarantee that, but it carries less of a</p> <p>6 risk of recall bias than retrospective</p> <p>7 data, correct?</p> <p>8 A. I'm just trying to think if</p> <p>9 that's always the case, but generally it's</p> <p>10 the case.</p> <p>11 Q. All right. And in O'Brien</p> <p>12 (2023), they found that there was evidence</p> <p>13 of a consistent answer between the first</p> <p>14 and second questionnaire, correct?</p> <p>15 MS. LEHMAN: Object to form.</p> <p>16 THE WITNESS: That really</p> <p>17 depends on how consistent you think</p> <p>18 things need to be to be consistent.</p> <p>19 BY MR. TISI:</p> <p>20 Q. It reported that there was --</p> <p>21 A. In terms of its -- in terms</p> <p>22 of its effect on recall bias, what really</p> <p>23 matters is not the kind of overall numbers</p> <p>24 that are consistent, but it's really the</p>	<p style="text-align: right;">Page 257</p> <p>1 time?</p> <p>2 MS. LEHMAN: I object to</p> <p>3 counsel's commentary.</p> <p>4 THE WITNESS: I mean, I'm just</p> <p>5 going to sort of, like, say that my</p> <p>6 answer was kind of like it depends,</p> <p>7 because part of it is what</p> <p>8 proportion --</p> <p>9 BY MR. TISI:</p> <p>10 Q. That's what they reported,</p> <p>11 I'm not asking you --</p> <p>12 MS. LEHMAN: Hold on. Let him</p> <p>13 finish. Let him finish.</p> <p>14 BY MR. TISI:</p> <p>15 Q. I'm not asking you the</p> <p>16 relevance, but he's not answering my</p> <p>17 question. I'm asking did they report --</p> <p>18 did they report that there was good</p> <p>19 correlation between the first and the</p> <p>20 second questionnaire in terms of reporting</p> <p>21 ever use?</p> <p>22 MS. LEHMAN: Object to form.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Whether you think it's</p>

<p style="text-align: right;">Page 258</p> <p>1 irrelevant or not, did they report that 2 there was good correlation? 3 A. I don't know if they used the 4 word "good," but I remember from we've just 5 looked at 87 percent was a number. 6 Q. Okay. 7 A. Whether you define that as 8 good or not depends on context -- 9 Q. Okay. 10 A. In my mind it also depends on 11 number of cases. I'm going to ask, because 12 I think you're kind of talking to me in a 13 rude way that I would really like a break 14 for five minutes at this point, so -- 15 Q. I'm not being rude, Doctor, 16 but you're really not answering my 17 questions. 18 MS. LEHMAN: Well, he really 19 is answering your questions -- 20 MR. TISI: Well, he's really 21 not -- 22 MS. LEHMAN: So let's just 23 take a break. 24 MR. TISI: Take a break.</p>	<p style="text-align: right;">Page 260</p> <p>1 was the result of the study, but otherwise, 2 I agree. 3 Q. And if you turn to Exhibit 4 No. 8, which is the O'Brien (2024) study, 5 on page 13, go to page 13, please, in the 6 middle paragraph, the paragraph beginning 7 with results. The last sentence says 8 "Analysis considering person-time accrued 9 since follow-up questionnaire completion 10 were not subject to recall bias, but had a 11 reduced sample size; estimates of the 12 genital talc and ovarian cancer association 13 were consistent with a positive 14 association," correct? 15 A. I agree that's what it says. 16 Q. Okay. So whether you're 17 looking at the 2023 study or the 2024 18 study, they were reporting that there was 19 good recall between the first and second 20 questionnaire, true? 21 A. I think what they're saying 22 there is that the analysis -- so I think 23 that was in your -- the table, yeah, that 24 you were previously pointing to, so that's</p>
<p style="text-align: right;">Page 259</p> <p>1 THE WITNESS: Can we take it 2 ten minutes? That would be useful. 3 MR. TISI: Sure. 4 - - - - - 5 (A recess was taken at this time.) 6 - - - - - 7 BY MR. TISI: 8 Q. Back on. All right. I'm 9 going to slow down. I'm told I'm going 10 fast, so I'm going to slow down and we will 11 regroup here. 12 Let me ask you these two 13 questions and I think we can move on if you 14 will agree with me that this is what the 15 authors say. Whether you agree with it or 16 not, you know, I get it. But the authors 17 in the 2023 study says that classification 18 of ever use of feminine hygiene products 19 may be recalled with good consistency, that 20 was the result of the 2023 patient study, 21 true? 22 A. I think there was a statement 23 of something to that effect in the 2023 24 study. I'm not entirely certain that that</p>	<p style="text-align: right;">Page 261</p> <p>1 the analysis in Table A2 on the right-hand 2 side, they say that it's not subject to 3 recall bias. They acknowledge it was a 4 reduced sample size. It's a much smaller 5 sample size and that there was their 6 estimate of the hazard ratio, the point 7 estimate was 1.84. 8 Q. And they make the further 9 statement on page 13 that that evidence was 10 consistent with a positive association of 11 fully prospective data, correct? 12 A. They may make that statement. 13 Do you want to highlight where it is 14 exactly? 15 Q. Yes, on page 13. I have it 16 highlighted and if you could blow it up, 17 Jeff. Blow up the page, please. "Analyses 18 considering person-time accrued since 19 follow-up question completion is not 20 subject to recall bias, but had a reduced 21 sample size; estimates of genital talc use 22 and ovarian cancer association were 23 consistent with a positive association," 24 true?</p>

<p style="text-align: right;">Page 262</p> <p>1 A. It is true that's what they 2 state. I don't know that I agree that they 3 can be certain that there's no recall bias 4 at all.</p> <p>5 Q. Okay. All right. So let's 6 talk a little bit about on page 14 of this 7 study, they say O'Brien (2024), they say 8 they overall, on the last paragraph, 9 "Overall, our findings support the 10 hypothesis that there is a positive between 11 genital talc use and ovarian cancer 12 incidence."</p> <p>13 Do you see that?</p> <p>14 A. I do agree that's what it 15 states, yes.</p> <p>16 Q. Okay. And --</p> <p>17 A. But they do qualify that 18 within there, there is still uncertainty as 19 to how much recall bias and missing data 20 could upwardly bias effect estimates, even 21 after doing their manipulation.</p> <p>22 Q. Okay. Do you agree with the 23 Sister Study investigators that the 24 question about lifetime use in the</p>	<p style="text-align: right;">Page 264</p> <p>1 Q. Okay. The second -- let me 2 just ask you this question. In several 3 places in your report, for example, 4 paragraph 18, but you use it other places 5 in 28 and 54, you said the NIH scientists 6 impute or assume whether a study subject 7 used genital talc for 38 percent of the 8 sample, but 54 percent of the ovarian 9 cancer cases.</p> <p>10 Do you recall that 11 statistic?</p> <p>12 A. I'm sorry, I remember the 13 general sort of statement. But I just want 14 to go to my report. So you said 15 paragraph 18?</p> <p>16 Q. Yes, that's the first place 17 where it appears. Go down please a little 18 bit, keep going. Are you on page 8 of your 19 report?</p> <p>20 A. Yeah.</p> <p>21 Q. "Under each of these 22 scenarios, the authors," very bottom, very 23 bottom, "Under each of these scenarios, the 24 authors impute, assume, or randomly select</p>
<p style="text-align: right;">Page 263</p> <p>1 follow-up questionnaire were effectively 2 broader than the use information inquired 3 about at enrollment?</p> <p>4 A. Not completely. I think they 5 were different. There was some ways in 6 which they, obviously, asked about the 7 additional interval, so in that sense, you 8 could argue they were broader. But in 9 other ways, they didn't offer as many 10 options for answers to questions. So 11 people could say don't know, for example, 12 so in that sense, they were narrower.</p> <p>13 They also didn't 14 specifically look at the age range 10 to 15 13, which would have made sense so that 16 they could carefully evaluate whether there 17 was agreement between the first and second 18 time points.</p> <p>19 Q. Well, they did do that in the 20 original douching study, in the 2023 21 douching study, right? They found an 22 87 percent correlation, true?</p> <p>23 A. They didn't ask about ages 10 24 to 13 at follow-up.</p>	<p style="text-align: right;">Page 265</p> <p>1 whether or not a participant used genital 2 talc in 38 of the sample, but 54 percent of 3 the ovarian cancer cases."</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. And you cited to Table A5 in 7 O'Brien (2024) and I cannot figure out how 8 you get those numbers, so if you would tell 9 me, I would appreciate it.</p> <p>10 A. Yeah, I can try to walk 11 through this.</p> <p>12 Q. And, Jeff, it's on the last 13 page of the document, last page of O'Brien, 14 yeah.</p> <p>15 A. Okay. So I certainly can't 16 do this by memory, but I have it in those 17 pie charts in my report that point to the 18 different rows, the header.</p> <p>19 Q. I mean, feel free to look at 20 your report. I just don't understand where 21 you get those numbers.</p> <p>22 A. Yeah. I will do. I want to 23 make sure I'm looking at the right --</p> <p>24 Q. If it makes it easier,</p>

<p style="text-align: right;">Page 266</p> <p>1 it's -- you refer to the same statistic on 2 page 18 -- paragraph 18, 28, and 54. 3 A. If you just give me a moment, 4 I'll be able to do it, I just need a 5 little -- I'm taking my glasses off because 6 the writing is small. So the eligible for 7 imputation part comes from row 4. 8 Q. Uh-huh. 9 A. And that's overall 19 and 37 10 in the ovarian cancer cases. Do you see 11 that okay? For the -- so eligible for 12 correction, that's rows two and five. So 13 it's three overall and five in ovarian 14 cancer cases. 15 And for the assumed, this 16 includes rows three and 12 added together. 17 Q. Okay. Did the authors 18 explain why they chose the 38 percent of 19 the sample? 20 A. I'm sorry, I didn't 21 understand. 22 Q. Let me rephrase it a 23 different way. 24 A. We chose a percent of the</p>	<p style="text-align: right;">Page 268</p> <p>1 they chose it on the basis of the states in 2 which they resided, true? 3 A. It's a bizarre question. I 4 mean, the 38 percent is the sample that 5 they have that they did these manipulations 6 on. 7 Q. Okay. 8 A. It doesn't matter what states 9 they came from. 10 Q. Okay. All right. So let's 11 talk about the kinds of -- 12 A. I want to be clear, they 13 didn't choose 38 percent. They took the 14 sample. 15 Q. They chose the cases that 16 comprised that 38 percent and they chose 17 them from nine states, correct? 18 MS. LEHMAN: Object to form. 19 THE WITNESS: I really don't 20 see how this relates to anything. 21 These are the -- 22 BY MR. TISI: 23 Q. Okay. 24 A. -- these are the controls and</p>
<p style="text-align: right;">Page 267</p> <p>1 sample -- 2 Q. They chose -- they chose the 3 38 percent of the sample that was genital 4 talc use based upon the states that they 5 resided in, true? There were nine states 6 that they resided in, not on the basis of 7 ovarian cancer status. 8 A. I'm really getting confused 9 with the question. Is there somewhere you 10 can refer to? 11 Q. I'm asking you, don't you 12 know that the 38 -- the authors calculated 13 the 38 percent on the basis of the nine 14 states they were in, not on their ovarian 15 cancer status? 16 MS. LEHMAN: Object to form. 17 THE WITNESS: Just point me 18 to, what's the 38 percent? 19 BY MR. TISI: 20 Q. I didn't get the number. You 21 calculated the number. I'm using the 22 38 percent number that you calculated, but 23 the reason they chose that 38 percent was 24 not on the basis of ovarian cancer status,</p>	<p style="text-align: right;">Page 269</p> <p>1 they had differential recall between them 2 and they did different things in the 3 controls and they did different things in 4 the cases and that affects the analysis. 5 Q. Let's talk about 6 contradictory data correlation correction 7 and missing data through multiple 8 imputation. Take out -- go to page 7 of 9 the O'Brien study, Table 2, if you don't 10 mind. 11 And table -- Scenario 4 12 includes both corrected for contradictory 13 data and multiple imputation, correct? 14 A. Well, I would argue that it's 15 not exactly, as I stated before, not really 16 correcting for contradictory data. It's 17 artificially changing data, but it is -- 18 Q. That's what the authors say? 19 A. It is labeled as correcting 20 contradictory data and multiple imputation. 21 Q. What they're trying to do is 22 deal with two different categories of women 23 in this study. The first is women who say 24 they were nonusers at enrollment, but who</p>

<p style="text-align: right;">Page 270</p> <p>1 said they were users in the follow-up 2 questionnaire so that they were considered 3 potentially contradictory, correct? 4 A. Yes, I mean, kind of, it's 5 correct, but I'm not -- they don't 6 explicitly state what they count as 7 contradictory or noncontradictory, but -- 8 and they do have these categorizations of 9 contradictory data versus noncontradictory. 10 Q. Okay. And just so we 11 understand that category, that category is 12 a woman who says I am a nonuser based upon 13 the first questionnaire, which has -- which 14 asks them about use between ages 10 and 13 15 and a year before enrollment, right? 16 A. Right. 17 Q. And then in a subsequent, if 18 they answered that question no in the 19 original questionnaire, but in a subsequent 20 questionnaire, they say yes, that qualifies 21 as contradictory, correct? 22 A. Here's the problem, they -- 23 they don't ask the same question. So in 24 the follow-up questionnaire, they have,</p>	<p style="text-align: right;">Page 272</p> <p>1 state, we read the sentence that says that 2 the second questionnaire, the specific 3 ages, age 10 and 13 and the last year and 4 did not capture lifetime exposure or use 5 during the most likely exposure period ages 6 20 through 39 years, right? 7 And in the previous douching 8 study, they said a woman could answer no to 9 the first question but yes to the second 10 question and really not be contradictory, 11 right? 12 A. Oh, so I do agree that it's 13 possible to answer no to the first 14 question, yes to the second, and it be not 15 contradictory, that's correct. 16 Q. But they're considering all 17 those women, to be careful, they're 18 considering all of those women to be 19 contradictory and then they apply their 20 analysis, which you disagree with, but 21 they're not trying to tease out which women 22 tried to answer the question consistently 23 or not. They're assuming they're all 24 inconsistent, correct?</p>
<p style="text-align: right;">Page 271</p> <p>1 like, 10 to 20. 2 Q. Right. 3 A. They ask about teens. Now, 4 is it contradictory or is it not 5 contradictory if they answer differently? 6 In one way, you might argue, it's not 7 contradictory if their use had been between 8 the ages of 14 and 20. If their use had 9 also been between 10 and 13, it would be 10 contradictory. We can't know that because 11 they don't ask suitable questions. 12 Q. And so -- and so -- 13 A. They don't state what -- so 14 you would have to make an assumption and 15 they don't say what that is. 16 Q. So what they're doing is if 17 somebody says no to the first questionnaire 18 but yes to the second questionnaire, they 19 are assuming those women are, quote, 20 "contradictory," even though in point of 21 fact they might not be? 22 A. They don't state that 23 anywhere. 24 Q. Well, but they do. They</p>	<p style="text-align: right;">Page 273</p> <p>1 MS. LEHMAN: Object to form. 2 THE WITNESS: I think that's 3 incorrect if we look, they have an 4 explicit category of nonuser at 5 enrollment, user at follow-up, 6 contradictory, and they have a 7 nonuser at enrollment, user at 8 follow-up, and whatever. The 9 opposite of whatever, if I said 10 noncontradictory, they also have a 11 contradictory group and they also 12 have a contradictory -- 13 BY MR. TISI: 14 Q. We'll have to forgive each 15 other -- we'll have to forgive each other, 16 because it is confusing, but what they're 17 doing is they're saying, look, we're going 18 to consider all the -- and we're going to 19 employ our assumptions to the data because 20 we are -- some of them are going to be 21 noncontradictory in fact, but some of them 22 are going to be contradictory unless they 23 use the 80/20, right? 24 A. Yeah, I'm not disputing that.</p>

<p style="text-align: right;">Page 274</p> <p>1 What I'm saying is that they're not clear 2 on the definition of not contradictory. 3 Q. Okay. 4 A. There are assumed situations 5 where they clearly are not contradictory, 6 like, in that example of the follow-up, 7 they said 20 to 30 and in the first one 8 they said, like, that they didn't use age 9 10 to 13 and if they're 12 months prior was 10 not in their twenties, then they would be 11 contradictory data. 12 Q. Right. 13 A. I don't know if they looked 14 at it in that way, so that would be not 15 contradictory. But when somebody says I 16 did use it at age 10 to 13, but then says 17 they or says I didn't -- the other way 18 around, I didn't use age 10 to 13, but I 19 used it between age ten to 20, is that 20 contradictory or not? 21 Q. And that's why they do what 22 they do, right, they acknowledge -- 23 A. They -- sorry. 24 Q. Right, but, again, I don't</p>	<p style="text-align: right;">Page 276</p> <p>1 is relegated to Table 2, which is the first 2 column, which is fully prospective, right? 3 A. Yes. 4 Q. Okay. And you describe that 5 in your paragraph 30 of your report, you 6 say that "O'Brien's baseline analysis has 7 two distinguishing features. First, it 8 uses only prospective information to assign 9 women to ever or never genital talc use," 10 and "Second that the baseline analysis 11 omits the smaller number of women who are 12 missing enrollment surveys about genital 13 talc use entirely," right? 14 A. Correct. 15 Q. All right. But there's a 16 third distinguishing factor between the 17 first and second questionnaire, and the one 18 that the authors highlight in their report, 19 correct, in their study, and that is that a 20 woman can answer the second questionnaire 21 yes and the first questionnaire no, and not 22 really be contradictory about how had they 23 ever used -- whether they ever used talc, 24 correct?</p>
<p style="text-align: right;">Page 275</p> <p>1 want to get to that next step. The first 2 thing is they identify two categories of 3 potential problems, one where there's 4 potential contradiction, true? 5 A. Yeah. 6 Q. Okay. And the second one is 7 where there's missing data, correct? 8 A. Yes. 9 Q. All right. And that would 10 be, for example, we talked about it before, 11 a woman who dies between the first and 12 second questionnaire and can't fill out the 13 second questionnaire, correct? 14 A. That would be one example. 15 Q. All right. And the authors 16 here separately tried to deal with those 17 two potential problems, right, 18 contradictory and then missing data, 19 correct? 20 A. They did take some steps to 21 try and do that. 22 Q. Okay. Now, you say in 23 paragraph 29 that the only truly reliable 24 data is the baseline analysis which you say</p>	<p style="text-align: right;">Page 277</p> <p>1 A. I don't think that's -- I 2 recall that as a distinguishing feature. 3 Q. They're two completely 4 different sets of questions, one was 5 limited and one was -- tried to capture 6 lifetime use, right? 7 A. I think there were two 8 different sets of questions that were not 9 well aligned and -- but I wouldn't call 10 that a distinguishing feature of the 11 baseline analysis. 12 Q. Okay. But they are 13 different, right? So the distinguishing 14 feature between the first and second 15 questionnaire is the second questionnaire 16 tried to get lifetime use and that's what 17 the authors said they were trying to get, 18 right? 19 A. I don't recall exactly what 20 the authors said, but they clearly looked 21 at different -- clearly had different 22 intervals within their follow-up survey. 23 It was more limited in some respects, but 24 it was more -- it had more intervals, but</p>

<p style="text-align: right;">Page 278</p> <p>1 they were different.</p> <p>2 Q. Okay. So let's talk about</p> <p>3 the contradictory data portion of the</p> <p>4 analysis that they did, the bias analysis</p> <p>5 that they did, okay?</p> <p>6 A. Okay.</p> <p>7 Q. All right. How many cases</p> <p>8 actually fell in that category, women that</p> <p>9 reported use -- they reported no use based</p> <p>10 upon the limited questionnaire 10 to 13 and</p> <p>11 a year before enrollment and the subsequent</p> <p>12 questionnaire which talked about use</p> <p>13 various time periods in their lifetime?</p> <p>14 A. Okay. So I would have to</p> <p>15 refresh my memory, because I don't remember</p> <p>16 the exact numbers. It's probably easiest</p> <p>17 to get it out. So I'm looking at Table A5,</p> <p>18 the last page of the exhibit, the O'Brien</p> <p>19 paper, if you can put that up on the</p> <p>20 screen. Unfortunately, the font is a</p> <p>21 little small.</p> <p>22 Q. Go to A5, please, Jeff.</p> <p>23 A. So and the relevant rows for</p> <p>24 correction are rows two and row -- row 2</p>	<p style="text-align: right;">Page 280</p> <p>1 data but assumes they were all unexposed,</p> <p>2 correct?</p> <p>3 A. So correct contradictory</p> <p>4 data, assume unexposed if unexposed at</p> <p>5 enrollment plus missing at follow-up.</p> <p>6 Q. So that's the outer range of</p> <p>7 contradictory data, so everybody is who</p> <p>8 reported nonuse at enrollment, but use</p> <p>9 later was actually nonusers, correct?</p> <p>10 MS. LEHMAN: Object to form.</p> <p>11 THE WITNESS: Maybe I'm</p> <p>12 misunderstanding.</p> <p>13 BY MR. TISI:</p> <p>14 Q. That's what it says, it says</p> <p>15 "correct contradictory data on assumed</p> <p>16 unexposed -- if unexposed at enrollment."</p> <p>17 That's what the column says, right and</p> <p>18 missing at follow-up?</p> <p>19 A. That's what the column says,</p> <p>20 yes.</p> <p>21 Q. Okay. And the outer limit,</p> <p>22 assuming everybody is not exposed, everyone</p> <p>23 did not take talc, right, where there was</p> <p>24 contradictory data, the risk was 1.17,</p>
<p style="text-align: right;">Page 279</p> <p>1 and row 5.</p> <p>2 Q. And how many patients -- how</p> <p>3 many women are there?</p> <p>4 A. I don't know the number of</p> <p>5 women off the top of my head. I would have</p> <p>6 to sit and do some math. They give the</p> <p>7 proportions here and they say 8 percent</p> <p>8 overall and nonusers at enrollment later</p> <p>9 said used with age reports -- I'm sorry,</p> <p>10 I'm looking at the wrong row, please. My</p> <p>11 error.</p> <p>12 Row 2, nonuser at</p> <p>13 enrollment, later said used at enrollment,</p> <p>14 eligible for correction, 3 percent overall</p> <p>15 versus 5 percent that were ovarian cancer</p> <p>16 cases.</p> <p>17 And then if we're looking</p> <p>18 in -- so in row 5, 7 percent overall, these</p> <p>19 are users at enrollment, never user at</p> <p>20 follow-up, eligible for correction, and</p> <p>21 overall 7 percent, but only 2 percent that</p> <p>22 are cases.</p> <p>23 Q. Now, if you go back to</p> <p>24 Table 2, Table 2 corrects contradictory</p>	<p style="text-align: right;">Page 281</p> <p>1 although not statistically significant,</p> <p>2 right?</p> <p>3 A. I don't know if I agree with</p> <p>4 your characterization of the outer risk</p> <p>5 thing.</p> <p>6 Q. Genital talc, let's call it</p> <p>7 genital talc, which is what you used.</p> <p>8 Genital talc, assume they're all unexposed,</p> <p>9 if unexposed at enrollment and missing at</p> <p>10 follow-up?</p> <p>11 A. Yes, so that applies just to</p> <p>12 the missing at follow-up data. They're</p> <p>13 basically saying, use the baseline value</p> <p>14 that we actually do have response for, yes.</p> <p>15 Q. Okay. And, similarly,</p> <p>16 category three kind of goes the other</p> <p>17 direction, right, it says assume they were</p> <p>18 all users?</p> <p>19 A. Yes, even though they never</p> <p>20 said at any time that they were users.</p> <p>21 Q. Right. So you have the two</p> <p>22 extremes, people who say they were never</p> <p>23 users, even though they were missing at</p> <p>24 follow-up and people who were, you assume,</p>

<p style="text-align: right;">Page 282</p> <p>1 that they were always users and that's the 2 bracket, right, 1.17 to 3.34, that's what 3 they talked about in categories three -- 4 two and three, right? 5 A. I disagree with that on a 6 couple of levels. So even if you accepted 7 the premise that these were extreme 8 bracketing scenarios, which I don't, and 9 I'll explain in a second, you really have 10 to look at the extremes of the confidence 11 intervals which tell you about the 12 plausible range of values. So we're really 13 going from .92 to 4.44 if you take that 14 whole thing as an extreme. 15 But there's already the 16 contradictory data correction here that 17 already brings in some bias in the upward 18 direction. You can see that because 19 Scenario 1 is lower with 1.07 and that in 20 turn brings in -- with its point estimate 21 and that in turn brings in some bias of its 22 own. And if you go back even further, you 23 go to Table A2 and that's the 1.02 -- 24 Q. But doesn't --</p>	<p style="text-align: right;">Page 284</p> <p>1 bias read potential. 2 BY MR. TISI: 3 Q. And so they asked in a 4 subsequent -- a subsequent questionnaire 5 whether they had ever used it, correct? 6 A. And, you know -- 7 Q. I'm just asking -- 8 A. I don't think it covers the 9 complete lifespan, I think there's -- 10 Q. Okay. But it covers -- 11 A. There's a wider lifespan I 12 would agree with. 13 Q. All right. Let's say that. 14 Just follow me here. Let me ask the 15 question and then if you need to explain 16 it, we'll do that. Okay? 17 A. Okay. 18 Q. You have a second 19 questionnaire which raises the possibility 20 that people who were originally classified 21 as nonusers were actually users, right? 22 A. It does raise the 23 possibility. 24 Q. Okay. So how would you --</p>
<p style="text-align: right;">Page 283</p> <p>1 A. The only one we can be sure 2 of, the one we can most sure of is not 3 suffering from biases and corrections and 4 manipulations and adjustments is Table A2. 5 Q. Well, except Table A2 -- 6 A. Why ruin a perfectly good 7 analysis by throwing -- 8 Q. I'll tell you why -- 9 A. -- your calculations in? 10 Q. I'll tell you why. Let me 11 give you a hypothetical as to why. We all 12 agree, I think we agreed at the outset, 13 that the original questionnaire did not ask 14 for lifetime use, right? 15 MS. LEHMAN: Object to the 16 commentary. 17 THE WITNESS: The original 18 questionnaire asked specifically 19 about ages 10 to 13 and the last 12 20 months. If they wanted to look at 21 something different, it's 22 unfortunate they didn't do a good 23 job of designing their study. So 24 it made that prospective recall</p>	<p style="text-align: right;">Page 285</p> <p>1 just follow me, okay, how would you as a 2 scientist have dealt with that question, 3 because it raises the question as to 4 whether or not -- whether or not the 5 original Gonzalez study was actually -- 6 really was ever use, right? And so now you 7 have data which indicates that people, 8 women may have actually used talc through 9 no fault of their own, right, but not 10 reported it, because of the way the 11 questions were asked. So what would you 12 do? Would you just throw out the study? 13 Would you throw out the subsequent 14 questionnaires? What would you do? 15 A. Oh, well, I mean, what I 16 would have done as a scientist, I mean, 17 obviously, I'm sitting here in a position 18 where I can retrospectively pontificate 19 about what I would have done. But the 20 first sort of, like, statement in response 21 to that is why you really ought to have 22 designed the study in the first place to 23 answer the questions you want to answer. 24 That's the whole point of a preeminent</p>

<p style="text-align: right;">Page 286</p> <p>1 specified analysis, plan, experimental 2 design. That's why you go through all of 3 that thinking and you say we need to make 4 sure we have the questions that will answer 5 the question you want to answer. 6 Q. Now, let's deal with reality. 7 Once you found out that the original 8 questionnaire doesn't ask the questions 9 that you thought that it answered, and you 10 find out through a subsequent questionnaire 11 that maybe a lot more people used talc than 12 originally reported, what would you have 13 done? 14 A. Okay. So, yeah, well, I kind 15 of have difficulties with that question, 16 again, on a few levels. 17 First of all, you know, 18 unfortunately the way science works is that 19 you can only answer what you can set up for 20 your design, your study, your data to 21 answer and if you mess things up in the 22 first place and circumstances change, there 23 may not be a way to get at a clean answer 24 that you want to get to and that's just --</p>	<p style="text-align: right;">Page 288</p> <p>1 Now, if somebody wants to 2 say, and just because you say I think 3 lifetime exposure is a more important 4 question, it's not a reason to withdraw a 5 paper. 6 Q. Okay. 7 A. I think there could have been 8 a better study design and that can be 9 argued, but it's not that the paper is 10 fundamentally wrong in what it's saying. 11 Q. But what they could do is 12 what they did, right, they published a 13 subsequent paper that published the data on 14 the follow-up questionnaire and discussed 15 the pros and cons of potential recall bias, 16 right? 17 A. They published a follow-up 18 paper and I think I'm very clear in my 19 report with what the problems are with this 20 follow-up paper. Again, you're trying to 21 solve a problem that I understand they want 22 to sort of be able to get at an analysis 23 that looks more at -- across a wider 24 lifespan, but if you just throw garbage</p>
<p style="text-align: right;">Page 287</p> <p>1 Q. So should they have 2 withdrawn, should the authors in your 3 opinion have withdrawn Gonzalez 2016 4 because it created a wrong impression? 5 A. Sorry, what did I say? Did I 6 say -- 7 Q. Do you think that the authors 8 should have either withdrawn the Gonzalez 9 study or published -- retracted it or 10 published a statement that said that study 11 may not have considered the entire lifetime 12 use of women and we don't -- we don't 13 represent that as being an entire lifetime 14 use of the women in the Sister Study? 15 A. Yeah, I don't want to -- we 16 can look at exactly what the wording is in 17 Gonzalez, but I think it very clearly 18 states what the questionnaire asks, that 19 it's asking about 10 to 13 versus last year 20 of use and it's a report that analyzes the 21 difference between exposed versus not 22 exposed, I mean, exposed in the paper. So 23 I don't think scientifically that's not 24 wrong.</p>	<p style="text-align: right;">Page 289</p> <p>1 into that to try to answer the question, 2 you're just going to get garbage out. 3 That's just the way it is. 4 Q. Okay. So you think the 5 subsequent questionnaire, to use your 6 phrase, was just garbage? 7 A. No, I think what's garbage -- 8 I think it was not -- what's garbage is the 9 level of missing data, the level of 10 imputation, the level of this switching of 11 data, all of these manipulations, they're 12 not -- 13 Q. Let's talk about missing 14 data -- 15 A. You want good data. You 16 don't want to have to do all that to the 17 data to the level they do. 18 Q. So you talked about 19 contradictory data and let's talk about 20 missing data and that's where they use 21 multiple imputation, correct? 22 A. Yes. 23 Q. Now, the missing data would 24 concern two categories, as I see it, a</p>

<p style="text-align: right;">Page 290</p> <p>1 woman who said they were nonusers on 2 enrollment or were missing a baseline, but 3 who for various reasons, including death, 4 didn't respond to the second questionnaire 5 so the data on lifetime use was missing; is 6 that right? 7 A. Well, they have, they have 8 the data from the baseline report -- 9 Q. Well, there was at least one 10 woman -- 11 A. What's missing is whatever 12 they've recorded at follow-up. 13 Q. Well, at least one woman had 14 been missing in baseline as well, right? 15 A. I think if they were missing 16 both at baseline and at follow-up, they 17 would just impute it at random for some 18 reason. 19 Q. Now, the NIH authors deal 20 with this missingness in Scenario 4 of 21 Table 2 through the multiple imputation 22 method that we talked about earlier that is 23 something that is recognized in the 24 statistical literature, correct?</p>	<p style="text-align: right;">Page 292</p> <p>1 MS. LEHMAN: Object to form. 2 THE WITNESS: I mean, I don't 3 recall exact words -- 4 BY MR. TISI: 5 Q. Let's look at paragraph -- 6 A. I don't doubt it I 7 potentially did refer to it as guessing. 8 Because there's an element of it that is 9 guessing, yes. 10 Q. Well, it's using statistical 11 methods to predict whether or not somebody 12 would be a user or a nonuser, right? It's 13 not guessing, correct? 14 A. If you have -- if you're 15 trying to predict something and you have 16 either very slightly related or bias -- 17 bias incorporated information that you're 18 using to predict that data, that's a guess. 19 Q. Well, wouldn't it also be a 20 guess if somebody answered on the initial 21 questionnaire that they were a nonuser 22 based upon the two limited categories, the 23 four years of a 74-year-old woman that they 24 were nonusers based upon the original</p>
<p style="text-align: right;">Page 291</p> <p>1 MS. LEHMAN: Object to form. 2 THE WITNESS: Multiple 3 imputation as a method is in the 4 statistical literature, it's a 5 method for imputing missing data. 6 But I think you linked it with the 7 first part of the question and I'm 8 not sure what the connection is. 9 BY MR. TISI: 10 Q. Well, you're not critical of 11 multiple imputation methodology as a 12 general matter, you're just critical of the 13 way in which the authors used it in this 14 case, right? 15 A. I'm critical of the 16 appropriateness of extrapolating so much 17 data and with -- in coming up with and then 18 relying on those results from the -- 19 Q. I'm sorry. You repeatedly 20 say throughout your report, and I don't 21 know how many times, but you repeatedly 22 said they guess and they assume genital 23 talc use and you use that in quotes 24 oftentimes throughout your report, correct?</p>	<p style="text-align: right;">Page 293</p> <p>1 questionnaire, that would be a guess, 2 right? 3 MS. LEHMAN: Object to form. 4 THE WITNESS: I'm sorry, are 5 you saying that -- 6 BY MR. TISI: 7 Q. Let me give you a 8 hypothetical -- 9 A. If you were trying to predict 10 whether somebody used it at age 74 based on 11 a question -- 12 Q. No, let me -- let me withdraw 13 the question and give you a hypothetical. 14 A 74-year-old woman enters 15 the study at baseline, I did not use it 16 between 10 and 13 and I did not use it at 17 age 73 to 74, right? 18 A. Okay. 19 Q. If you do not use multiple 20 imputation or some method to try to deal 21 with the missingness question, let's say 22 she dies, okay, aren't you guessing that 23 she was in fact a nonuser between age 13 24 and 73?</p>

<p style="text-align: right;">Page 294</p> <p>1 A. If you were doing an analysis 2 between ages 13 and 73 -- 3 Q. Right. So -- 4 A. -- you would be -- 5 MS. LEHMAN: Hold on. Hold 6 on. Let me him finish. 7 THE WITNESS: But there is no 8 analysis between those ages and 9 then the analysis at baseline is 10 very consistent across everybody. 11 It's asking the same question as 12 everybody. It's not -- this is 13 where kind of the whole problem 14 here is they're trying to combine 15 information from Scenario 1 that 16 asks one set of questions with 17 information from Scenario 4 that 18 has a whole bunch of missing data 19 with different questions. They're 20 trying to glue that together and 21 it's like trying to fit a square 22 peg in a round hole. It doesn't 23 work. 24</p>	<p style="text-align: right;">Page 296</p> <p>1 Q. I understand. I understand. 2 A. You're trying to make me do a 3 comparison between -- 4 Q. No, no, no. I'm not. I'm 5 really not. I'm asking a very specific 6 question. With regard to missingness, 7 forget about all the other problems you 8 think permeated this data, let's deal with 9 missingness alone, don't you agree with me 10 that it would be arbitrary to assume in 11 category -- in Scenario 2 that all those 12 women would be nonusers as arbitrary as 13 saying in category three all the women 14 would be users? 15 MS. LEHMAN: Object to form. 16 THE WITNESS: No, because 17 here's the problem, what's your 18 definition of a nonuser and a user 19 here? 20 BY MR. TISI: 21 Q. Lifetime use. Lifetime use. 22 Somebody who uses it lifetime but we have 23 missing data. 24 A. All right. So what do you</p>
<p style="text-align: right;">Page 295</p> <p>1 BY MR. TISI: 2 Q. Isn't it true that the 3 statistical literature says that it is 4 simply wrong to assume somebody is, in this 5 case, for example, a nonuser, that multiple 6 imputation, for example, is a much more 7 credible way of dealing with missing data 8 in that scenario? 9 A. I totally did not understand 10 that question. 11 Q. Well, would you agree with 12 me, let's -- it would be arbitrary, let's 13 use this to be specific, would you agree 14 that it would be arbitrary to assign all 15 women in the Sister Study as either 16 lifetime talc nonusers as was done in 17 Scenario 2 or lifetime talc users as was 18 done by the authors in Scenario 3, just 19 assign them -- 20 A. I mean -- 21 Q. -- missing data? 22 A. Here's my problem. My 23 problem is that Scenarios 1, 2, 3, and 4 24 are all poor analyses.</p>	<p style="text-align: right;">Page 297</p> <p>1 have here, what do you have to answer that 2 question? 3 Q. You have multiple imputation, 4 which is what the authors did. 5 A. No, no -- 6 Q. So -- well, let me ask you 7 this. 8 A. You asked me a question and 9 you didn't let me answer. 10 Q. Okay. Well, go ahead, finish 11 the answer. 12 A. Right, so you have a 13 baseline. You have relatively complete 14 data, but it is only answering, as you say, 15 10 to 13 and the last year, but it's 16 relatively complete. At follow-up, you 17 have highly incomplete data, you have so 18 much missing data, and it's not missing at 19 random, and multiple imputation is not 20 going to get you to the right answer, 21 because you do not have a completely 22 predictive model of what's going on. You 23 do not have missing at random even, which 24 is let alone --</p>

<p style="text-align: right;">Page 298</p> <p>1 Q. We'll talk about that --</p> <p>2 A. -- random. You do not have</p> <p>3 predictors outside of your outcome that are</p> <p>4 predictive of whether or not somebody is</p> <p>5 missing. And you also have in your data</p> <p>6 highly differential exposures, exposure</p> <p>7 missingness in cases versus controls. That</p> <p>8 should set all alarm bells ringing that you</p> <p>9 can't do this. You can't get away this and</p> <p>10 have a reasonable analysis. You can't come</p> <p>11 up with reliable numbers based on that.</p> <p>12 Q. Let me --</p> <p>13 A. So I understand that you</p> <p>14 don't believe that the analysis in A2 is</p> <p>15 answering the question you want to answer,</p> <p>16 but neither is the data that -- you can't</p> <p>17 get there with this incomplete, poorly</p> <p>18 acquired data that has differential</p> <p>19 missingness, all kinds of biases thrown in,</p> <p>20 and do these contradictory manipulations</p> <p>21 and kind of solve the problem and it goes</p> <p>22 away.</p> <p>23 Q. Let's look at Exhibit No. 21</p> <p>24 and see if you will agree with this. This</p>	<p style="text-align: right;">Page 300</p> <p>1 Do you agree with that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Now at the end of this</p> <p>4 sentence, at the end of the paragraph, it</p> <p>5 says "When missing data occur, it is</p> <p>6 important not to exclude cases with missing</p> <p>7 information (analyses after such exclusion</p> <p>8 are known as complete case analyses)."</p> <p>9 Do you see that?</p> <p>10 A. I see that's what it states.</p> <p>11 Q. Do you agree with that? You</p> <p>12 don't exclude them?</p> <p>13 A. I think it's important not to</p> <p>14 blindly exclude them.</p> <p>15 Q. Okay. It goes on to say --</p> <p>16 A. I do not agree with this</p> <p>17 statement overall. I think it's missing</p> <p>18 that qualifier.</p> <p>19 Q. Okay. They go on to say</p> <p>20 "Single-value imputation methods are those</p> <p>21 that estimate what each missing value might</p> <p>22 have been and replace it with a single</p> <p>23 value in the data set.</p> <p>24 "Single-value imputation</p>
<p style="text-align: right;">Page 299</p> <p>1 is a "JAMA Guide to Statistics and Methods,</p> <p>2 Multiple Imputation, A Flexible Tool for</p> <p>3 Handling Missing Data by Li, Stewart, and</p> <p>4 Allison."</p> <p>5 Do you see that?</p> <p>6 A. Yes, I see the page.</p> <p>7 -----</p> <p>8 (JAMA Article marked Kornak</p> <p>9 Exhibit 21 for identification.)</p> <p>10 -----</p> <p>11 BY MR. TISI:</p> <p>12 Q. And have you seen this paper</p> <p>13 before?</p> <p>14 A. I actually don't recall</p> <p>15 whether I've seen it before or not. I</p> <p>16 don't remember it.</p> <p>17 Q. Could you blow it up, please,</p> <p>18 Jeff?</p> <p>19 MR. WRIGHT: It should be</p> <p>20 there.</p> <p>21 BY MR. TISI:</p> <p>22 Q. It's not. I can't see it.</p> <p>23 It says, if you look at Exhibit No. 21, it</p> <p>24 says "Missing data are common in research."</p>	<p style="text-align: right;">Page 301</p> <p>1 methods include mean imputation, last</p> <p>2 observation carried forward, and random</p> <p>3 imputation."</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. Do you agree with that?</p> <p>7 A. Yes, I mean, there's</p> <p>8 potentially other ways to do it as well,</p> <p>9 but those are examples of single value</p> <p>10 imputation.</p> <p>11 Q. It goes on to say "These</p> <p>12 approaches can yield biased results and are</p> <p>13 suboptimal. Multiple imputation better</p> <p>14 handles missing data by estimating and</p> <p>15 replacing missingness -- missing values</p> <p>16 many times."</p> <p>17 Do you see that?</p> <p>18 A. I do see that.</p> <p>19 Q. Do you agree with that</p> <p>20 generally speaking?</p> <p>21 A. Even a simplistic way, but</p> <p>22 there's sort of caveats as to when that</p> <p>23 completely holds.</p> <p>24 Q. Okay. Let's go to the next</p>

<p style="text-align: right;">Page 302</p> <p>1 page. It says "What are the limitations of 2 Multiple Imputation?" First of all, have 3 you ever written a paper like this where 4 you talk about the method of multiple 5 imputation? 6 MS. LEHMAN: Objection. Asked 7 and answered. 8 THE WITNESS: Well, I would 9 argue this is not really -- this is 10 kind of an opinion piece and no, 11 I'm not in the practice of writing 12 opinion pieces. 13 BY MR. TISI: 14 Q. Okay. Well -- all right. 15 It's actually, it says it's a JAMA Guide to 16 Statistics and Methods, but we'll let it 17 stand what it is. 18 A. No, I would say that's just 19 the journal name, right? It's not the 20 title of the paper or -- 21 Q. Okay. The paragraph on the 22 left side, says "Many nonstatisticians 23 chafe at making up data," that's what 24 you're accusing the authors here of doing,</p>	<p style="text-align: right;">Page 304</p> <p>1 manipulate too filling these gaps 2 in the data. 3 BY MR. TISI: 4 Q. You're basically saying they 5 didn't trust the women when they answered 6 the 10 to 13 and the year before question 7 to deal with the missingness question, 8 right? 9 A. I don't -- I think that 10 mischaracterizes what I state. I mean, I 11 think, like, they clean data a baseline 12 that is relatively complete. They impute 13 data at follow-up and they do it in a way 14 where they're taking people that said they 15 never used at baseline and they're using an 16 imputation approach that incorporates 17 recall bias from the follow-up study that 18 they're using to build the multiple 19 imputation model and then they're kind of 20 baking that into their imputation process. 21 Q. Right. Okay. And what 22 you're saying is they should have just 23 trusted the women who answered I didn't use 24 it at 10 to 13, and the year before, and</p>
<p style="text-align: right;">Page 303</p> <p>1 right, making up data? 2 MS. LEHMAN: Object to form. 3 THE WITNESS: What I'm 4 accusing that the -- and accusing 5 is not the right word, I'm, when 6 criticizing the paper and saying 7 that there was data manipulation, 8 improper imputation, and assumption 9 that were beyond reasonable. 10 BY MR. TISI: 11 Q. Well, you go actually further 12 than that, Doctor, and to be clear, I mean, 13 just to be fair, you say, you know, they 14 don't trust the women on their original 15 questionnaire and that they impute data in 16 the study based upon not missingness in the 17 second questionnaire that they never filled 18 out, right? 19 A. They kind of do, yes, some 20 kind of manipulation -- 21 Q. Okay. So you think -- 22 MS. LEHMAN: Hold on. Hold 23 on. Let him finish. 24 THE WITNESS: And they do</p>	<p style="text-align: right;">Page 305</p> <p>1 assume that they were nonusers, right? 2 A. I don't believe I'm even 3 saying that. I'm suggesting that the whole 4 follow-up analysis is flawed because of the 5 level of missing data, the level of bias 6 that's in there. It's just too problematic 7 to fix. 8 Q. Okay. 9 A. Not at missing, not at random 10 situation, that's basically where you are, 11 you're in a hole -- 12 Q. Let's read this paragraph and 13 see what you think about it. It says "Many 14 statisticians chafe at making up data as is 15 done in MI and note that the validity of 16 MI, multiple imputation, depends on an 17 assumption about which factors relate to 18 the probability that a data point is 19 missing. Because of concern this 20 assumption may be violated. It is tempting 21 to retreat to the safe haven of complete 22 case analysis, i.e., only analyze the 23 participants without missing values." 24 Isn't that what you're</p>

<p style="text-align: right;">Page 306</p> <p>1 saying, just look at the women who -- just 2 look at the women who answered the 3 question -- 4 A. That's not what I'm saying. 5 Q. Okay. "The safe haven is 6 however, illusory. Although rarely made 7 explicit by the users, complete case 8 analysis requires a far more restrictive 9 assumption: That any data point missing is 10 missing completely at random. Other common 11 strategies, mean imputation, last 12 observation carried forward and other 13 single imputation approaches underestimate 14 standard errors by ignoring or 15 underestimating the inherent uncertainty 16 created by missing data, a problem multiple 17 imputation helps overcome." 18 Do you agree with that? 19 A. I agree there are certain 20 situations where that is true, that 21 multiple imputation certainly helps -- 22 Q. Now, you criticized -- 23 A. -- but there are real 24 problems here with using it. I think where</p>	<p style="text-align: right;">Page 308</p> <p>1 from the data, true? 2 A. Only if that information is 3 explanatory about your missingness in a way 4 that's unbiased and reasonable. If it 5 was -- if it did it as you describe 6 perfectly, we wouldn't need to collect all 7 the data, we would just collect parts of 8 data and just fill it all in with multiple 9 imputation. Clearly, it's better to have 10 complete data. 11 Q. Well, but you can't -- 12 A. You're always losing when you 13 have to start imputing, and when you have 14 to impute a lot, you get into a lot of 15 trouble. 16 Q. I mean, look, in fairness, 17 most missing data was because women died as 18 a result of ovarian cancer, correct? 19 A. I mean, I don't know what 20 proportion of the missing, the differential 21 missingness of the cases was due to people 22 dying. I have no doubt that some 23 proportion of that at least would be 24 because of that. It doesn't change the</p>
<p style="text-align: right;">Page 307</p> <p>1 I think it mischaracterizes what I'm 2 suggesting is that I'm not suggesting that 3 they treat the follow-up analysis as a 4 complete case analysis, far from it, that 5 would also be terrible. That would be like 6 Scenario 5, it would be awful. 7 Scenario 1, however, has 8 many more missing data and even though 9 O'Brien with that missing data effectively 10 treats it as if it was complete case 11 analysis for that missing data, because 12 they just basically impute based on those 13 proportions at random. That's equivalent 14 almost to treating it as if it had been a 15 complete case analysis on those people 16 missing at both time points. 17 I'm not suggesting in any 18 way that you take the data from time point 19 four and treat that as a complete case 20 analysis. There's just too much missing. 21 It would be terrible. 22 Q. Missing imputation takes the 23 guesswork out of data when data is missing 24 using statistics we actually know about</p>	<p style="text-align: right;">Page 309</p> <p>1 fact that, and that's unfortunate, 2 obviously, it's terribly unfortunate, but 3 in terms of the analysis, it still leaves 4 you in trouble. 5 Q. So one of the big criticisms 6 you have, as I read it, for example, in 7 paragraph 44, but in your circular logic 8 section of your report, is that the authors 9 included outcome status or cancer status in 10 their imputation model; is that true? 11 A. Yes. 12 Q. Okay. And -- 13 A. It says -- I'm trying to go 14 to the paragraph, I mean, I agree with 15 you -- 16 Q. For example, paragraph 44, 17 but you have a whole section on that 18 beginning on Section C, "O'Brien's Chosen 19 Imputation Method is Inappropriate for the 20 dataset used," and you talk about how they 21 used, I'm sorry, page 25 of your report, 22 Section 8, "O'Brien Relies on Circular 23 Logic to Impute Genital Talc Use," and you 24 talk about inclusion of cancer status as</p>

<p style="text-align: right;">Page 310</p> <p>1 part of the model there as well.</p> <p>2 A. Right.</p> <p>3 Q. Okay. So one of your main</p> <p>4 criticisms and one repeated throughout your</p> <p>5 report is that they used cancer status in</p> <p>6 the model and that biases the hazard ratio</p> <p>7 away from one, right?</p> <p>8 A. Right.</p> <p>9 Q. And you think that is an</p> <p>10 absolutely wrong way in which to do</p> <p>11 imputation and that's a fatal flaw of this</p> <p>12 study, true?</p> <p>13 A. Well, I think that</p> <p>14 exaggerates what I'm saying. I think I</p> <p>15 would want to qualify that. You can in</p> <p>16 multiple imputation use the outcome to do</p> <p>17 some imputation. You have to be careful,</p> <p>18 but if you know that your outcome has bias</p> <p>19 baked in, then you're just going to</p> <p>20 reinforce it. That's the circularity. If</p> <p>21 your outcome doesn't have any bias baked</p> <p>22 in, you would be fine. Now, whether that's</p> <p>23 because of people, more cases dying or not,</p> <p>24 for the purposes of it being a problem here</p>	<p style="text-align: right;">Page 312</p> <p>1 course, that never exists. You're always</p> <p>2 suboptimal to that. But that is the kind</p> <p>3 of situation where you would be more</p> <p>4 comfortable with your missing imputation</p> <p>5 approach.</p> <p>6 Q. Well, isn't it true that the</p> <p>7 authors of the 2024 article explain why</p> <p>8 they include outcome status in their model</p> <p>9 and actually cite a paper for that?</p> <p>10 A. I don't recall exactly what</p> <p>11 they said to justify using the outcome in</p> <p>12 their model.</p> <p>13 Q. Well, let's look at it --</p> <p>14 A. Citing a paper, you can</p> <p>15 always cite a paper for anything, the</p> <p>16 point, but does it justify what your --</p> <p>17 Q. Well, let's look at what they</p> <p>18 said. I mean, the question is whether or</p> <p>19 not their methods are reasonable, right? I</p> <p>20 mean, whether you would do it or not is</p> <p>21 kind of irrelevant. The question is did</p> <p>22 they employ methods that are commonly used</p> <p>23 in the statistical community, true?</p> <p>24 MS. LEHMAN: Object to form.</p>
<p style="text-align: right;">Page 311</p> <p>1 is to some degree irrelevant, because you</p> <p>2 do have the differential missingness. It's</p> <p>3 there in the data. It's almost double in</p> <p>4 the cases of what it is in the controls, so</p> <p>5 your imputation process is going to bake</p> <p>6 all that back into the imputation part.</p> <p>7 Q. But, Doctor, isn't it true</p> <p>8 that the imputation, the multiple</p> <p>9 imputation would be a fatal mistake to not</p> <p>10 include outcome status in the imputation</p> <p>11 model?</p> <p>12 A. Actually, I mean, no, the</p> <p>13 ideal situation with multiple imputation is</p> <p>14 that you have other variables, covariates</p> <p>15 that could perfectly explain your</p> <p>16 missingness that would not be related to</p> <p>17 the outcome so that you don't risk any kind</p> <p>18 of feedback error. But it's all other</p> <p>19 covariates, other examples, demographic</p> <p>20 variables that could fully explain the</p> <p>21 missingness. That's the perfect scenario</p> <p>22 where you would be as if you didn't have</p> <p>23 missing data. Because you would be able to</p> <p>24 perfectly predict the missingness. Of</p>	<p style="text-align: right;">Page 313</p> <p>1 THE WITNESS: No, I think the</p> <p>2 question is do the methods they use</p> <p>3 appropriately solve the problem so</p> <p>4 that they can make unbiased</p> <p>5 inferences in the data that they</p> <p>6 have.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Okay. Well, they, on page 4</p> <p>9 of their -- of their study, if you would go</p> <p>10 back to Exhibit No. 8.</p> <p>11 A. Yes, I'm there.</p> <p>12 Q. They have a paragraph on the</p> <p>13 right-hand side that talks about multiple</p> <p>14 imputation under the methods section and</p> <p>15 describes how they -- how they perform the</p> <p>16 data. Could you blow that up, just that</p> <p>17 paragraph up, if you don't mind, Jeff?</p> <p>18 Okay. In the paragraph, it says "We</p> <p>19 included all the previously described</p> <p>20 confounders and covariates in the</p> <p>21 imputation model, as well as the cancer</p> <p>22 outcomes and crude cumulative hazard</p> <p>23 estimates, which corresponded to the hazard</p> <p>24 of the earliest of the three cancer</p>

<p style="text-align: right;">Page 314</p> <p>1 events." 2 Do you see that? 3 A. Yes. 4 Q. Now, the three cancer events 5 they were looking at was breast cancer, 6 uterine cancer, and ovarian cancer, right? 7 A. I believe so. 8 Q. All right. And so they're 9 including -- and this is something you 10 criticized them for, right? 11 A. What's the "this" that -- 12 Q. That they're including the 13 outcome increased this feedback loop that 14 you've talked about, that including cancer 15 status as part of their imputation model 16 exaggerates the hazard ratio, right? 17 A. Correct. 18 Q. All right. But they actually 19 cite a paper in support of why they did 20 what they did, right? 21 A. You mean the citation number 22 32 there? 23 Q. Correct. It's the Royston 24 and White paper, correct?</p>	<p style="text-align: right;">Page 316</p> <p>1 identification.) 2 ----- 3 BY MR. TISI: 4 Q. Okay. And this is the paper 5 upon which the authors rely for including 6 cancer status in their multiple imputation 7 model, correct? 8 A. I think they use the paper to 9 try and point out -- to kind of, like, say 10 what the method is that they're using for 11 kind of incorporating that data rather than 12 as a justification, but -- 13 Q. Well, they're basically 14 saying we applied, we applied a multiple 15 imputation methodology that was in the 16 published literature and here it is at 17 footnote 42 for the world to see, right? 18 They just didn't say it without 19 attribution, true? 20 A. Yeah, again, they're just 21 saying this is the way they dealt with the 22 incorporating the outcome into their 23 imputation log. 24 Q. So now let's look at whether</p>
<p style="text-align: right;">Page 315</p> <p>1 A. Yes, they cite that paper. 2 Q. Right. And in fact, not only 3 do they cite -- 4 A. I don't -- I'm sorry. 5 Q. And not only do they cite the 6 paper, you have it on your reliance list, 7 correct, not reliance list, but a paper you 8 considered? 9 A. Yes. 10 Q. All right. And you don't 11 discuss that paper at all in your report, 12 do you? 13 A. No. 14 Q. No, you don't, so let's see 15 what that paper actually says. 16 A. Do we have this? 17 Q. We do. I'm going to get it 18 for you. I'm a little bit ahead of myself 19 in my outline. Would you go to Exhibit 20, 20 please? 21 A. Yes. 22 ----- 23 (Royston and White Paper 24 marked Kornak Exhibit 20 for</p>	<p style="text-align: right;">Page 317</p> <p>1 or not -- what this paper says. 2 A. Uh-huh. 3 Q. Right. And you did not 4 discuss this in your report, did you? 5 MS. LEHMAN: Objection, asked 6 and answered. 7 THE WITNESS: I don't believe 8 I discussed it in any way. I just, 9 like I said, I looked at it, I saw 10 what the kind of point of the 11 referencing it was. They use 12 software that uses this to 13 incorporate their outcomes. 14 BY MR. TISI: 15 Q. Right. And they -- and you 16 didn't say, well, you know, Royston and 17 White might have been correct here, but 18 maybe not there, you didn't address it in 19 any way, did you? 20 A. I mean, White and Royston 21 here are providing a method to incorporate 22 outcomes, survival outcomes within multiple 23 imputation. It's a methodology thing. 24 Q. Let's see what they say. I'm</p>

<p style="text-align: right;">Page 318</p> <p>1 sorry, let's see what they say. It says 2 multiple imputation -- can you please 3 scroll up, please? "Multiple imputation is 4 commonly used to impute missing data, and 5 is typically more efficient than complete 6 cases analysis in regression analysis when 7 covariates have missing values. Imputation 8 may be performed using a regression model 9 for the incomplete covariates or other 10 covariates and, importantly, on the 11 outcome." Right? Correct? 12 A. Yeah, the qualifier there is 13 it may be performed. 14 Q. Well, and then it says 15 importantly, includes the outcomes, right? 16 A. Again, linked with the word 17 "may," you may include the outcome. 18 Q. Right. And it goes on to say 19 "We compare the methods using simulation 20 studies. We find that using log T biases 21 covariate-outcome association towards the 22 null, while the new methods have lower 23 bias." 24 Do you see that?</p>	<p style="text-align: right;">Page 320</p> <p>1 BY MR. TISI: 2 Q. Well, let's continue. It 3 says here on page 1983. "When the 4 incomplete data are covariates in the 5 analysis model, the analysis model outcome 6 must be used to predict the missing 7 covariate values. Although this practice 8 may seem counterintuitive, it is in fact 9 essential," correct? 10 A. I would really have to sit 11 with this and look at the context. So if 12 you want to give me a minute to read the 13 paragraph before and after, I'm happy to do 14 that, but I'm not going to -- 15 Q. Did you read this paper? I 16 mean, this is the paper upon which they 17 relied to perform the multiple imputations 18 that they did for missing data. This was 19 the only paper that they relied on. Did 20 you look at it? 21 MS. LEHMAN: Object to form. 22 Asked and answered. 23 THE WITNESS: Yes, I looked at 24 it. I didn't go through it in</p>
<p style="text-align: right;">Page 319</p> <p>1 A. Yes. 2 Q. And they go on to say 3 "Overall, we recommend including event 4 indicator and the Nelson-Aalen estimator in 5 the imputation model." 6 Do you see that? 7 A. Yes. 8 Q. Go down please, a little 9 further. 10 A. But I'm going to qualify it, 11 they're not saying that you should do that 12 when your outcome has bias already induced 13 in it. 14 Q. I understand, but you've 15 criticized them, you've criticized the 16 authors here for daring to include an 17 outcome in their imputation model and this 18 article says you need to. If you're going 19 to do it, you need to include the outcome, 20 correct? 21 MS. LEHMAN: Object to form. 22 THE WITNESS: I don't think it 23 says that. 24</p>	<p style="text-align: right;">Page 321</p> <p>1 detail. 2 BY MR. TISI: 3 Q. Okay. 4 A. I looked through it just -- 5 it's kind of a tangential. They are giving 6 this as a reference because it's the 7 approach that the software that they use, I 8 believe they use, they would have used as a 9 status SSR and that software uses this in 10 how it puts things together and they would 11 have used it. I don't think when they are 12 referencing this paper they're saying look 13 at this to justify our incomplete data. 14 Q. On what basis would you 15 say -- on what basis do you say -- they 16 say, they cite this paper for including all 17 the covariates as well as the outcomes in 18 their multiple imputation model. They cite 19 it for that purpose. 20 A. I don't believe that's what 21 they do -- 22 Q. Well, let's go back and see 23 what they say. Go back to the paper, on 24 page 4, it says "We included all of the</p>

<p style="text-align: right;">Page 322</p> <p>1 previously described confounders and 2 covariates in the multiple imputation, as 3 well as each of the cancer outcomes in the 4 crude cumulative hazard estimates." 5 Citation White and Royston. 6 A. That's for the method of 7 using the crude cumulative hazard estimate. 8 Q. Right, for cancer -- 9 A. It doesn't say we justify our 10 use of the outcome based on this paper. I 11 mean, like I say, I'm happy to read through 12 those paragraphs if you want me to to put 13 them into context. 14 Q. Let's go back to the Royston 15 article, the White and Royston article. 16 A. Yeah. 17 Q. They say failure to include, 18 while it may be counterintuitive, failure 19 to include outcomes is essential, true? 20 MS. LEHMAN: Objection. The 21 article speaks for itself. 22 BY MR. TISI: 23 Q. If you're going to do it, you 24 need to include outcomes, right?</p>	<p style="text-align: right;">Page 324</p> <p>1 now? This is a good time to take a break. 2 Why don't you take a look at the paper at 3 the break? 4 A. You know what, that could be 5 great. I would appreciate that. Thank 6 you. 7 Q. No problem. 8 ----- 9 (A recess was taken at this time.) 10 ----- 11 BY MR. TISI: 12 Q. Doctor, we have been talking 13 about the White and Royston article. We 14 gave you an opportunity to go off the 15 record and read it. Have you had an 16 opportunity to read it? 17 A. I believe I've had an 18 opportunity to scan it, yes. 19 Q. Yeah. And I think before you 20 had indicated that you had not really, I 21 think, read it in detail previously, is 22 that true or had you read it in detail? 23 A. I think I would say that 24 statement still holds, it's a deeply</p>
<p style="text-align: right;">Page 323</p> <p>1 MS. LEHMAN: Same objection. 2 THE WITNESS: I'm going to 3 look at that, I mean, if you -- 4 BY MR. TISI: 5 Q. Great. 6 A. Are you just reading out the 7 statement to me or are you -- 8 Q. I'm reading, I mean, it's a 9 pretty clear statement, it says, when -- 10 A. No, no, no, no -- 11 Q. Well, let's -- 12 A. -- it's not. You cannot -- 13 you cannot look at a complex, statistical 14 methodological paper and then just say, oh, 15 you can just read this and understand it 16 and interpret it. 17 Q. That's fine. Take a look at 18 it, but they say when incomplete data are 19 covariates in the analysis -- 20 A. I saw the piece that you 21 highlighted, but I would like to, like, 22 quietly read the previous and the 23 following. 24 Q. Why don't we take a break</p>	<p style="text-align: right;">Page 325</p> <p>1 math -- it's a mathematically, technical 2 paper that goes into some simulation 3 studies, just from now from my quick look, 4 you know, that would be a paper that would 5 take days to carefully look at. 6 Q. And you didn't do that before 7 you rendered your opinion about the 8 feedback loop, right? 9 A. No, and I don't think this 10 paper is relevant to that -- 11 Q. Okay. 12 A. -- statement. 13 Q. So having now had an 14 opportunity to review the paper, and if you 15 put it up again, it says, the article says 16 "When the incomplete data are covariates in 17 the analysis model, the analysis model 18 outcome must be used to predict the missing 19 covariate values. Although this practice 20 might be counterintuitive, it is in fact 21 essential." And actually has a footnote to 22 another paper. 23 Do you see that? 24 A. I do.</p>

<p style="text-align: right;">Page 326</p> <p>1 Q. Do you agree or disagree with 2 that statement? 3 A. I don't know that I either 4 agree or disagree. Well, I certainly am 5 not going to argue it, but I would say this 6 is conditional, based on what I've seen in 7 the simulation studies, quickly looking 8 through, on outcome data not incorporating 9 bias in any way. And also that -- and as 10 is required for all multiple imputation 11 models to -- with a basic assumption that 12 you are in a missing at random situation 13 not a missing not at random situation. 14 Q. Well, we -- 15 A. Here the problem is that the 16 second time point values being incorporated 17 into the imputation model incorporates 18 bias. So I would stand by that statement. 19 The exact details here of what they -- why 20 they say must be and essential, I would 21 defer answering. 22 Q. Well, I mean, if I'm 23 understanding this correctly and I'm just, 24 you know, I'm just a lawyer, right, so I'm</p>	<p style="text-align: right;">Page 328</p> <p>1 in favor of null, correct? 2 A. I would agree that it's of 3 interest whether bias -- any bias is bad. 4 Q. Right. 5 A. We can agree to that, I 6 think. And bias whether that's bias 7 towards the null or bias away from the 8 null, bias away from the null is the most 9 dangerous though when you are considering 10 statistical inference and whether or not to 11 reject a null hypothesis. For example, if 12 you're trying to get a drug approved with 13 FDA, they're not going to worry too much 14 about you having bias towards the null. 15 They're going to be much more worried about 16 you having bias away from the null. 17 Q. Right. And it's not like the 18 authors here did not consider the potential 19 of bias. We're going to talk about that in 20 a moment, but the question higher with the 21 multiple imputation is really just 22 calculating the hazard ratio and then after 23 that considering whether or not it's the 24 result of bias, right? I mean, the first</p>
<p style="text-align: right;">Page 327</p> <p>1 trying to understand this, but if I 2 understand this question correctly, 3 imputation doesn't go to the question 4 about -- you always have to answer the 5 question about bias, right? Imputation 6 just deals with the question of 7 missingness, am I right? 8 A. Well, imputation is about 9 trying to fill in missing data as -- 10 Q. Correct. 11 A. -- best you can in a way that 12 your analysis is as unbiased as it can be. 13 But that is separate, like, the missing 14 data approach can incorporate bias and then 15 it becomes a problem. 16 Q. And then you always have 17 to -- you always have to account for bias, 18 right? I mean, even whether it's a bias 19 away from the null or towards the null, you 20 always have to, when you're doing 21 statistical analysis of this type, you 22 know, question one is how did you calculate 23 the hazard ratio; and two, does it 24 incorporate bias either away from null or</p>	<p style="text-align: right;">Page 329</p> <p>1 question is -- 2 A. No, no. 3 Q. If I'm understanding 4 correctly -- let me rephrase the question. 5 A. Okay. 6 Q. If I'm understanding the 7 process, the first thing that they did was 8 do a quantitative bias analysis to 9 calculate a hazard ratio. And the second 10 question is acknowledging the potential for 11 recall bias, how do they address that 12 question. They're really two separate 13 questions, right? 14 MS. LEHMAN: Object to form. 15 THE WITNESS: I don't know 16 that they're separate. It's like 17 bias upon bias, that one part of 18 the bias is the part that they do 19 the -- what they call a correction 20 for. And then they do the 21 imputation incorporating that bias 22 and rolling it in and baking it in 23 and amplifying it. And then they 24 do this, oh, but what if some of it</p>

<p style="text-align: right;">Page 330</p> <p>1 is recall bias and we'll kind of 2 play around with some numbers that 3 we make up of what it might be. 4 BY MR. TISI: 5 Q. Right. But the first 6 question really is, and just to be, just so 7 we have a clear record, what they're doing 8 with the quantitative bias analysis is 9 accounting for contradictory missing data 10 in order to calculate a risk ratio, 11 correct? 12 A. I don't think they're 13 accounting for anything. I mean, 14 accounting and statistics, accounting for 15 something means incorporating it into the 16 model as something that you're estimating 17 in some way, typically, as part of the 18 modeling procedure. They're not doing that 19 here. They're just changing data. 20 Q. And to be clear, Doctor, when 21 somebody does a multiple imputation, they 22 don't know ahead of time how it's going to 23 affect the hazard ratio, do they? They 24 don't know if it's going to go towards the</p>	<p style="text-align: right;">Page 332</p> <p>1 A. I'm just going to think 2 through that. I think if you had just -- 3 yeah, in a very general sense, if you -- if 4 you have a complete -- if you just use the 5 complete case analysis like they did, we 6 can even go back to, was it Table 3 with 7 the final row that you were describing the 8 analyses that they only look after the 9 follow-up time, do you remember? 10 Q. Yeah. 11 A. If we go to it, yeah. 12 Q. No -- 13 A. Go ahead. 14 Q. No. I mean, I guess I'm 15 trying to get at the concept that White and 16 Royston make on page 1983, it says 17 important -- they say "it is important to 18 find the right way to include the survival 19 outcome in the imputation model because, 20 otherwise, the association between the 21 covariate and the surveillance survival is 22 likely to be diluted." 23 A. Right, but you're diluting, 24 like in that, it's -- that statement is</p>
<p style="text-align: right;">Page 331</p> <p>1 null or away from the null, it could go 2 either way. 3 A. I mean, relative to what, 4 relative to if they did a complete case 5 analysis, you mean, or relative to what? 6 Q. They don't know, what I'm 7 trying to say is there's no way to predict 8 what the results of the imputation process 9 is going to be in terms of amplifying or 10 tamping down the hazard ratio, correct? 11 A. I don't agree with that, 12 because if you know about sources of bias, 13 then you can start to predict the 14 direction, you could have predicted the 15 direction here based on their steps. If 16 you looked at the data that they have just 17 in the tables and you know what the steps 18 are they're going to do, you know that 19 these steps will bias you away from the 20 null. 21 Q. Well, wouldn't not including 22 the survival status or the outcome in the 23 model have biased the results towards the 24 null?</p>	<p style="text-align: right;">Page 333</p> <p>1 true. I think there's an important caveat 2 there of finding the right way to include 3 the survival outcome. 4 And then there's another 5 important aspect to this is you're diluting 6 what you have, but in the complete data 7 analysis that you're starting from that you 8 would be diluting in the O'Brien (2024) 9 paper with starting using only follow-up, 10 only -- let's say you were using that 11 example of the -- you're starting from the 12 follow-up time point and you're looking 13 prospectively, then there's only -- you 14 have limited data there because of weak -- 15 well, because of -- partly possibly because 16 of whatever answer you get there, if you 17 then impute missing data that will get 18 biased, that move towards the null. I 19 don't think bias at the right word, but it 20 will move towards the null -- 21 Q. Let me see if I can put it 22 another way. The authors here -- I'm 23 sorry. I'm sorry. The authors here 24 described a method including cancer status</p>

<p style="text-align: right;">Page 334</p> <p>1 in the imputation model and they cite, I 2 think I said it wrong before, I said 42, I 3 think I meant footnote 32, which is the 4 White and Royston model. Okay? You would 5 not include cancer status in the imputation 6 model because it would create this feedback 7 loop, right? 8 A. Because you're in the kind 9 of -- you're in the missing not at random 10 situation, yeah, you have bias in that 11 data, yes. 12 Q. So what is your authority 13 for, I mean, if I'm reading this paper 14 correctly and I'm just a lawyer, right, I'm 15 reading this saying although this practice 16 of including cancer status in an imputation 17 model, this may seem counterintuitive is in 18 fact essential, right, when I read that, I 19 need to take the opposite point of view 20 that putting cancer status would amplify 21 the risk and, therefore, should not be 22 included and I want to know, you know, your 23 authority, is there a textbook, an article 24 or something where you can say, point me to</p>	<p style="text-align: right;">Page 336</p> <p>1 going to incorporate that bias into your 2 imputation. I mean, that's -- 3 Q. Would you go to -- 4 A. The simulations that they 5 have here in White and Royston do not 6 incorporate those kinds of biases, they're 7 simulations under ideal missing at random 8 situations and where they do not have bias 9 in their outcomes. 10 Q. So I'm going to look at, and 11 can we go to your number 42 in your report, 12 please, where you talk about MICE 13 procedure. Do you see -- 14 A. I'm sorry, I'm still getting 15 there. In my 42, I don't see that, no. 16 Q. It says -- I'm sorry? 17 A. I say, I'm talking about 18 imputations later, but -- 19 Q. Let me ask you this, will the 20 MICE procedure classify all women as talc 21 users? The MICE procedure is a predictive 22 model that will classify women as users and 23 some women as nonusers, right? 24 A. Clearly, it doesn't, because,</p>
<p style="text-align: right;">Page 335</p> <p>1 that is the counter to White and Royston? 2 A. Well, White and Royston is 3 under the assumption that missing multiple 4 imputation is appropriate, which is the 5 missing at random situation. 6 Q. Okay. 7 A. Under that -- under that 8 assumption, and if your outcomes are 9 unbiased, I mean, I don't -- there is -- 10 and so Rubin's book will tell you you can't 11 use multiple imputation if you're missing 12 not at random. 13 Q. Okay. 14 A. You can go all the way back 15 there and you can look at every textbook on 16 multiple imputation, it says if you have 17 missing not at random, multiple imputation 18 as it stands is inappropriate. 19 Then there's also -- I don't 20 know if you'll find a textbook, but there's 21 an implicit assumption that your data that 22 you have is right and not biased. And if 23 you do have biased data that you're 24 building your imputation model from, you're</p>	<p style="text-align: right;">Page 337</p> <p>1 otherwise, it would be the same as Scenario 2 3. 3 Q. Well, okay. But -- 4 A. We would get exactly the same 5 answer, because you would get exactly the 6 same data as you imputed in Scenario 3. 7 Q. To be clear, using MICE on 8 this dataset was never going to be and did 9 not in fact classify all talc -- all 10 ovarian cancer cases where there was 11 missing data as nonusers or as users? 12 A. I'm just trying to follow the 13 logic through and there's -- 14 Q. Let me rephrase my question. 15 A. I think most likely not, but 16 there is a bizarre scenario where you 17 classified all the cases as one thing and 18 all the non-cases were mixed up, but it 19 would be very bizarre. 20 Q. Well, in fact, multiple 21 imputation takes the guesswork out of data 22 analysis when data is missing using data 23 that statisticians do in fact know about to 24 predict in this case use or nonuse, right?</p>

<p style="text-align: right;">Page 338</p> <p>1 A. I would qualify that, it 2 tries to. 3 Q. Okay. 4 A. It depends on whether you 5 have the information to do that. 6 Q. Right. 7 A. There are other variables. 8 Q. And in this case, you have 9 not, to my knowledge, attacked the 10 proprietary, other than cancer outcome, of 11 the variables used by the authors to 12 predict whether or not a woman is nonuser 13 or user in the case of missingness? 14 A. I think I do point to it, if 15 you go to paragraph, I think it's 54, going 16 on to the top of page 25. So these are -- 17 these are the variables they're using for 18 multiple imputation beyond an outcome, at 19 least some of them, and you see, like, 20 across the board, they're really small 21 correlations and so you can't predict -- 22 you can't predict the missingness when 23 there's such little information in the 24 covariate. You can't predict it well. So</p>	<p style="text-align: right;">Page 340</p> <p>1 each of your imputed datasets and you're 2 building your confidence intervals from 3 those. 4 The more uncertainty there 5 is, the more imputations you need to get a 6 representative sample of that missingness. 7 Q. Right, so it won't cause -- 8 A. But in practice, it's very 9 hard to sort of, like, run more than, you 10 know, ten imputations. It's an expensive 11 computational process. 12 Q. Well, it won't cause bias 13 actually by, even if they were not good 14 predictors, the variables used, they would 15 just cause variance, for example, multiple 16 imputations will accurately convey how much 17 information there actually is in the data 18 about the relationships, true? 19 A. I didn't say they would cause 20 bias. These, the non-outcome related 21 predictors, if they're measured well, will 22 not cause bias. They just won't provide 23 any information about what the missing 24 value is.</p>
<p style="text-align: right;">Page 339</p> <p>1 you're taking a little bit of the guesswork 2 out maybe if these estimates are real and 3 not just sort of, like, noise in the data. 4 But you're only going to be predicting a 5 little bit. 6 Q. Well, isn't it okay, and I'm 7 probably using the wrong word 8 statistically, but isn't it all right if 9 they aren't good predictors, because in 10 that circumstance, multiple imputations 11 will be variable across imputations and it 12 will just increase the uncertainty or the 13 width of the confidence interval? 14 A. That's certainly part of it, 15 but it's not the complete story. So you 16 can get to a point where you're adding in 17 variables and you're adding in noise into 18 the process. Also, when you do multiple 19 imputation, if you're to have -- you have 20 to do some combination across imputations. 21 So, like, I think the others talk about 22 using Rubin's rules to do that, my 23 understanding is there are other 24 approaches, but, you know, basically taking</p>	<p style="text-align: right;">Page 341</p> <p>1 Q. And that in fact -- 2 A. It's basically just 3 simulating it completely at random. 4 Q. And that's a big problem with 5 single imputation, since basically it 6 pretends that each value is true but is not 7 a problem with multiple imputation because 8 that's the whole kind of point of doing it, 9 right, multiple imputations -- 10 A. I'm not going to argue -- I'm 11 not arguing that single imputation is 12 better by a long way and that also has, you 13 know, the only reason that single 14 imputation gets used anymore for super 15 massive datasets, where it's just 16 computationally too expensive to do any 17 other kind of imputation. But what I am 18 saying here is that, okay, just if you're 19 setting your bar super low and you're 20 saying we can beat that bar a little bit by 21 having these only very slightly related 22 variables to the potential for missingness, 23 that doesn't really get you very far. 24 Q. But, again, I mean, the</p>

<p style="text-align: right;">Page 342</p> <p>1 actual variables used are disclosed in the 2 paper, I think it's footnote D of the 3 table. I've got to find my copy of it. 4 It's contained in footnote D of Table 2, 5 correct? 6 A. In footnote -- 7 Q. Two, I have it on the screen 8 as well, if it that helps locate it. 9 A. No, I've located it, it's 10 just small writing. So it lists additional 11 variables used over and above those that 12 are used for the survival analysis, but 13 it's not completely clear what are the 14 variables that come from the survival 15 analysis. So it's not clear that we have a 16 complete list here. 17 Q. Again, you don't know the 18 answer to that question, so it's -- 19 A. Well, no, the answer to that 20 question is that it's incomplete. 21 Q. Okay. So my question though 22 is they've disclosed the imputation model 23 including both the variables that they used 24 and the outcome status in their article,</p>	<p style="text-align: right;">Page 344</p> <p>1 BY MR. TISI: 2 Q. Have you done that? 3 A. Have I searched their 4 website -- 5 Q. Have you looked -- 6 A. -- as to whether they tell 7 you what imputation model they used in a 8 paper that should have included that 9 information? I did not do that, no. 10 Q. Well, okay. You know, I 11 mean, you've written papers before and I'm 12 sure people could always say that more 13 could have been included that wasn't, 14 right, you've heard that before, right? 15 A. Yeah, I'm not going to 16 dispute that there are papers that I have 17 been involved in that there are certain 18 aspects that are -- that some detail that 19 may have been missed. But here -- 20 Q. Right. 21 A. -- there are just so many, on 22 so many levels, there are stuff missing 23 that it goes beyond my analysis. 24 Q. I understand, I get it. I</p>
<p style="text-align: right;">Page 343</p> <p>1 including the reasons why they did it, 2 true, they cited White and Royston? 3 A. They don't completely 4 disclose the predictors in the multiple 5 imputation model, because they're saying 6 they use it, what they had in the 7 multivariable analysis, which they don't 8 completely specify. In addition, those two 9 pieces, even if they were complete, would 10 not completely describe the imputation 11 process, because they don't say what kind 12 of model they use for the imputation. Are 13 they using logistic regression, probit 14 regression? There are multiple ways of 15 imputing a binary variable and they don't 16 say what -- 17 Q. Have you searched -- have you 18 searched the website for the Sister Study 19 to see whether or not that data is 20 available? 21 MS. LEHMAN: Object to form. 22 THE WITNESS: It's not data, 23 it's a model. 24</p>	<p style="text-align: right;">Page 345</p> <p>1 get it. And you've identified those -- you 2 have identified those in eight days after 3 \$50,000, right? 4 MS. LEHMAN: Object to form. 5 Argumentative. 6 THE WITNESS: I identified 7 those pieces that I found within my 8 report after performing an 9 independent review of this paper. 10 BY MR. TISI: 11 Q. And that was your charge, 12 right? Tell me what's wrong with this 13 paper. 14 MS. LEHMAN: Object to form. 15 THE WITNESS: I said before, I 16 was asked to give an independent 17 review of this paper. That's what 18 I did. 19 BY MR. TISI: 20 Q. If you were asking for an 21 independent review, did you say, you know, 22 I'm going to do this, I'm going to do this 23 for free, because I'm interested in the 24 topic? It's not completely independent,</p>

<p style="text-align: right;">Page 346</p> <p>1 let's be fair, true?</p> <p>2 MS. LEHMAN: Object to form.</p> <p>3 Argumentative. Asked and answered.</p> <p>4 BY MR. TISI:</p> <p>5 Q. When you say it's</p> <p>6 independent --</p> <p>7 A. I would not be doing this if</p> <p>8 I was not paid. I would not be doing my</p> <p>9 work as a professor if I was not paid for</p> <p>10 it.</p> <p>11 Q. All right.</p> <p>12 A. So it's not my hobby, right.</p> <p>13 Q. But your work as a professor</p> <p>14 is not being paid by a company who is</p> <p>15 defending their product, true? Your work</p> <p>16 as a professor is to --</p> <p>17 A. I'm actually trying to think</p> <p>18 of whether there are situations in my work</p> <p>19 as a professor where, I mean, so certainly</p> <p>20 there are, you know, in my work in</p> <p>21 dementia, we're doing things related to</p> <p>22 clinical trials which are in the interest</p> <p>23 of companies, so.</p> <p>24 Q. So we talked about -- we have</p>	<p style="text-align: right;">Page 348</p> <p>1 A. We've talked about the steps</p> <p>2 they took to come up with that number and</p> <p>3 what they claim is an analysis of recall</p> <p>4 bias.</p> <p>5 Q. Well, that's the second step</p> <p>6 that they did, they acknowledged the</p> <p>7 potential because they were using</p> <p>8 retrospective data in the -- they used</p> <p>9 prospective data from the initial</p> <p>10 questionnaire and retrospective data from</p> <p>11 the supplemental questionnaire and then</p> <p>12 they tried -- they calculated their hazard</p> <p>13 ratio, but they did more recall bias,</p> <p>14 didn't they?</p> <p>15 A. At what point are you saying</p> <p>16 they didn't --</p> <p>17 Q. Well, they acknowledge the</p> <p>18 potential for recall bias and then tested</p> <p>19 the hazard ratio to see whether or not</p> <p>20 reasonably there would be a -- that the</p> <p>21 risk was likely related to recall bias,</p> <p>22 correct?</p> <p>23 A. I would dispute the word</p> <p>24 "reasonably" there. I think here what</p>
<p style="text-align: right;">Page 347</p> <p>1 been talking about recall bias all day in</p> <p>2 the context of the bias analysis that came</p> <p>3 to category four in Table 2, the 1.81</p> <p>4 hazard ratio, correct?</p> <p>5 A. Well, I think there's two</p> <p>6 pieces here. What they call quantitative</p> <p>7 bias analysis is really their manipulation</p> <p>8 of outcomes, what they call a correction.</p> <p>9 And then the recall bias is another step</p> <p>10 kind of on top of that afterwards, but</p> <p>11 those two things combined are indeed in</p> <p>12 their Scenario 4.</p> <p>13 Q. So, right, so what I really</p> <p>14 want to focus on, I spent time talking</p> <p>15 about how they came up with the 1.81 hazard</p> <p>16 ratio for the relationship between talc and</p> <p>17 ovarian cancer --</p> <p>18 A. Just to be clear for, like,</p> <p>19 do you mean the 1.82 point in Scenario 4?</p> <p>20 Q. I'm sorry, you're correct,</p> <p>21 you're correct. Actually, it's -- yes,</p> <p>22 correct. And we have been talking about</p> <p>23 how they came up that number acknowledging</p> <p>24 the potential for recall bias, correct?</p>	<p style="text-align: right;">Page 349</p> <p>1 we're -- if we're still talking about</p> <p>2 Table 2, there's no -- none of their -- the</p> <p>3 recall bias step is not yet entered when</p> <p>4 we're here. This is just their</p> <p>5 contradictory data manipulation plus</p> <p>6 multiple imputation. Then later on, they</p> <p>7 have in Figure 2, their recall bias, what</p> <p>8 they call scenarios, which is really their</p> <p>9 what-if situations.</p> <p>10 Q. All right. They say --</p> <p>11 A. What do you mean by</p> <p>12 "reasonable"?</p> <p>13 Q. Well, they're saying that</p> <p>14 they're basically taking their data and</p> <p>15 they're saying what if there is recall</p> <p>16 bias, would we still have a positive</p> <p>17 association, correct?</p> <p>18 A. They are trying to do this</p> <p>19 through their random flipping process.</p> <p>20 Q. Okay. And throughout your</p> <p>21 report, you talk about recall bias, but it</p> <p>22 is in fact a theoretic concern, true?</p> <p>23 MS. LEHMAN: Object to form.</p> <p>24 Asked and answered.</p>

<p style="text-align: right;">Page 350</p> <p>1 BY MR. TISI:</p> <p>2 Q. In other words, recall bias</p> <p>3 is a theoretical concern that those who</p> <p>4 have the disease may differentially recall</p> <p>5 an exposure compared to those who don't</p> <p>6 have the disease, correct?</p> <p>7 MS. LEHMAN: Same objection.</p> <p>8 THE WITNESS: Are we talking</p> <p>9 about in this situation here or --</p> <p>10 BY MR. TISI:</p> <p>11 Q. I'm talking about generally.</p> <p>12 Generally, recall bias is a theoretical</p> <p>13 concern that those who have a disease may</p> <p>14 differentially recall an exposure as</p> <p>15 compared to those who do not have the</p> <p>16 disease?</p> <p>17 A. I don't know that.</p> <p>18 MS. LEHMAN: Same objection.</p> <p>19 THE WITNESS: That's a theory.</p> <p>20 I think it's something that exists</p> <p>21 in many problems.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Right. And we know that</p> <p>24 there are many, many scientists who</p>	<p style="text-align: right;">Page 352</p> <p>1 data regarding talc use in the -- it says</p> <p>2 there was evidence in the Sister Study that</p> <p>3 recall bias was not as significant as to</p> <p>4 contaminate the data, correct? You use the</p> <p>5 word "contamination." In fact, we talked</p> <p>6 about some of the issues before. They did</p> <p>7 the recall paper in 2023 where they said it</p> <p>8 was consistency in recall of talc use.</p> <p>9 They looked at the subset of people whose</p> <p>10 data was truly prospective and saw a</p> <p>11 positive hazard ratio, although</p> <p>12 statistically not significant.</p> <p>13 So they had evidence that in</p> <p>14 this particular population, there was not</p> <p>15 the evidence of recall bias that would make</p> <p>16 this data unusable, true?</p> <p>17 MS. LEHMAN: Object to form.</p> <p>18 THE WITNESS: That was a very</p> <p>19 long question and I think you begun</p> <p>20 by saying that there's some -- you</p> <p>21 try to imply that there's some</p> <p>22 level of recall bias that this is</p> <p>23 below such that it doesn't</p> <p>24 contaminate the data. You know, if</p>
<p style="text-align: right;">Page 351</p> <p>1 question whether or not recall bias really</p> <p>2 is as significant as, for example, you are</p> <p>3 saying it is, true?</p> <p>4 A. I don't know what they're</p> <p>5 calling significant versus what I'm saying</p> <p>6 it is. I don't know. I haven't argued</p> <p>7 with anybody about it. I really don't --</p> <p>8 the question is just super vague.</p> <p>9 Q. Okay. Well, in this case,</p> <p>10 the authors of O'Brien (2024), these NIH</p> <p>11 scientists, did not ignore the potential</p> <p>12 for recall bias using the supplemental</p> <p>13 questionnaire in conjunction with the</p> <p>14 enrollment questionnaire, did they?</p> <p>15 A. I mean, they took these steps</p> <p>16 where they did things and then they did</p> <p>17 these what-if adjustments for whatever</p> <p>18 proportions might be recall bias of</p> <p>19 different scenarios that did they -- they</p> <p>20 didn't -- I mean, it's here in the paper,</p> <p>21 so they didn't, like, ignore recall bias as</p> <p>22 being a thing. I mean, they acknowledge</p> <p>23 it's a problem.</p> <p>24 Q. But they also noted that the</p>	<p style="text-align: right;">Page 353</p> <p>1 there's any recall bias, it's</p> <p>2 contaminating the data. It's a</p> <p>3 question of what level.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Right. And when they looked</p> <p>6 at that question objectively, they</p> <p>7 published a paper in 2023 which indicated</p> <p>8 that that was not a big problem with this</p> <p>9 particular dataset, true?</p> <p>10 A. I know, I accept that that's</p> <p>11 their conclusion. I mean, basically, is</p> <p>12 that -- first of all, I don't see how they</p> <p>13 could possibly assess a precise measure of</p> <p>14 recall bias when there's no matching</p> <p>15 questions between the two surveys. They</p> <p>16 don't match. They don't align. Even if</p> <p>17 they did align, thus, pointing to</p> <p>18 87 percent agreement, that's 13 percent</p> <p>19 disagreement. And that's proportionately</p> <p>20 affected in the cases. That can lead to a</p> <p>21 very big amount of recall bias.</p> <p>22 Q. Have you done the math to see</p> <p>23 how much -- how much -- have you done the</p> <p>24 math to see how much recall bias would be</p>

<p style="text-align: right;">Page 354</p> <p>1 introduced by a 13 percent mismatch?</p> <p>2 A. I don't need to, because I</p> <p>3 actually have the data here in O'Brien</p> <p>4 (2024) that tells us what the recall -- the</p> <p>5 differential recall actually is here. You</p> <p>6 can see it in table -- in Table A5, row 4,</p> <p>7 that in overall, 19 percent said nonuser at</p> <p>8 enrollment, missing at follow-up.</p> <p>9 Thirty-seven percent of cases, that's</p> <p>10 basically kind of you double the non-cases</p> <p>11 are missing at follow-up after saying they</p> <p>12 were nonuser at enrollment. That's</p> <p>13 differential recall.</p> <p>14 Q. Well, they may be missing in</p> <p>15 follow-up, Doctor, because they died,</p> <p>16 right?</p> <p>17 A. But that's still the same</p> <p>18 problem for the analysis.</p> <p>19 Q. Well, it's not, that's why</p> <p>20 you use multiple imputation, correct?</p> <p>21 A. No --</p> <p>22 MS. LEHMAN: Object to form.</p> <p>23 BY MR. TISI:</p> <p>24 Q. The data is missing and now</p>	<p style="text-align: right;">Page 356</p> <p>1 studies, and I'll represent to you that</p> <p>2 both, and I talked about this before, both</p> <p>3 the Nurses' Study and the Women's Health</p> <p>4 Initiative used a questionnaire after the</p> <p>5 study began to talk about telecues. It</p> <p>6 happens all the time, true?</p> <p>7 A. I would want to look at the</p> <p>8 specifics of those questionnaires, because</p> <p>9 there's two different ways you can look at</p> <p>10 data after the start point of the study.</p> <p>11 There is kind of like retrospective asking</p> <p>12 of questions of what was or this</p> <p>13 longitudinal data gathering where you're</p> <p>14 updating information as you go along.</p> <p>15 That's different than trying to --</p> <p>16 Q. I understand. I get it. I</p> <p>17 get it. But if -- what I'm trying to get</p> <p>18 at here is retrospective data is used by</p> <p>19 epidemiologists and statisticians all the</p> <p>20 time, true?</p> <p>21 A. Well, statisticians analyze</p> <p>22 retrospective data. Epidemiologists look</p> <p>23 at retrospective data. It's generally</p> <p>24 preferred to have prospective data. It</p>
<p style="text-align: right;">Page 355</p> <p>1 you want to look and see whether or not the</p> <p>2 data you have predicts them as being a user</p> <p>3 or nonuser, true?</p> <p>4 A. No, this is exactly what I'm</p> <p>5 saying, it introduces the missing not at</p> <p>6 random. You can't just blindly apply</p> <p>7 multiple imputation. This is your problem.</p> <p>8 This is one of the problems that I talked</p> <p>9 about, and then also incorporating the</p> <p>10 correct and contradictory data,</p> <p>11 incorporating the manipulation of data,</p> <p>12 this is all in there. It's a problem. You</p> <p>13 can't just -- you can't wave a magic wand</p> <p>14 and fix this.</p> <p>15 Q. Okay. You know that</p> <p>16 epidemiologists use retrospective data all</p> <p>17 the time, true?</p> <p>18 A. They use --</p> <p>19 Q. A control study is a</p> <p>20 retrospect study?</p> <p>21 A. Yes, retrospective for this</p> <p>22 study. And they're also always qualified</p> <p>23 by the limitations of being retrospective.</p> <p>24 Q. Sure. Right. Even cohort</p>	<p style="text-align: right;">Page 357</p> <p>1 doesn't mean, like, retrospective data is</p> <p>2 something you can learn from, but --</p> <p>3 Q. And prospective data --</p> <p>4 A. -- but you're facing</p> <p>5 limitations when you do that.</p> <p>6 Q. Prospective data has its own</p> <p>7 limitations, for example, prospectively</p> <p>8 collected data can introduce differential</p> <p>9 misclassification, true, misclassification?</p> <p>10 A. The same with retrospective</p> <p>11 data.</p> <p>12 Q. Right. And so you always</p> <p>13 have to be careful about biases. It's not,</p> <p>14 like, one study design is better than</p> <p>15 another. You have to basically look at the</p> <p>16 strengths and weaknesses of each study and</p> <p>17 then look at it in the context of</p> <p>18 everything else that happened, true?</p> <p>19 MS. LEHMAN: Object to form.</p> <p>20 THE WITNESS: That's true, but</p> <p>21 it's also true that, you know, that</p> <p>22 there's still a difference in the</p> <p>23 level here. And when you're doing</p> <p>24 things prospectively, there is a</p>

<p style="text-align: right;">Page 358</p> <p>1 risk of if any bias of it being 2 towards the null, but that's not 3 what you're mostly -- so all bias 4 is bad, it's better to not have 5 bias, I acknowledge that, but the 6 biggest concern is bias away from 7 the null because that's what leads 8 to spurious results. That is the 9 big concern. That's what the 10 reproducibility crisis is all 11 about. It's artificial detection 12 of effects where none exist. 13 BY MR. TISI: 14 Q. Now, looking at the O'Brien 15 study, O'Brien (2024), they did the whole 16 thing, they did -- they dealt with bias, 17 they did a bias analysis and they did their 18 recall bias analysis and they said that was 19 their main objective, true? 20 A. I don't see that they said 21 that. 22 Q. Look at page 2 of the O'Brien 23 study. 24 A. I see "Key objective, are</p>	<p style="text-align: right;">Page 360</p> <p>1 which is about their main objective and 2 then the second sentence is what they tried 3 to do to try to deal with problems that 4 they knew they were incorporating by 5 reevaluating using the follow-up data. 6 Q. And when we talk about 7 retrospective studies, they also talk about 8 the problems with prospective studies in 9 the sentence above, "Although not affected 10 by recall bias, prospective studies tend to 11 have small case numbers and simplified 12 exposure assessments, resulting in low 13 statistical precision and increased 14 likelihood of nondifferential exposure 15 misclassification." That's true, right? 16 A. I mean, that's quite a 17 generalization that isn't true always. You 18 can have prospective studies -- 19 Q. They said tend to have. They 20 didn't say always, they say they tend to 21 have? 22 A. It's still a generalization. 23 I don't know. I haven't seen this study 24 that analyzes, like, a random sample of</p>
<p style="text-align: right;">Page 359</p> <p>1 history of genital talc use and 2 douching associated with breast --" 3 Q. Go to page 2, go down on the 4 left-hand side, "Our main objective was to 5 reevaluate the associations between 6 intimate care product use and incidence of 7 hormone-related cancers, expanding on 8 previous analyses, by incorporating newly 9 diagnosed ovarian and uterine cancers, 10 adding breast cancer as an outcome, and 11 integrating new data on lifetime use of 12 douche and genital talc. Because the newly 13 acquired exposure data were susceptible to 14 differential missingness by cancer status, 15 we used quantitative bias analysis to 16 estimate effects under several missingness 17 assumptions. When examining the 18 association between genital talc use and 19 ovarian cancer, we additionally evaluated the 20 potential of recall bias," true? 21 A. That's what that paragraph 22 says, but I want to just make a distinction 23 between the first sentence there, they're 24 very long sentences, but the first sentence</p>	<p style="text-align: right;">Page 361</p> <p>1 prospective studies and a random sample of 2 retrospective studies to determine the 3 number of cases. I just want to point out, 4 I wouldn't really try to argue too much -- 5 Q. All right. 6 A. -- I mean, if -- there are 7 certainly situations where you have a 8 retrospective, you choose to do a 9 retrospective analysis because in that 10 situation, you might be able to get higher 11 case numbers than you could if you tried to 12 run a prospective study, because it might 13 take you 50 years to get that number of 14 cases. And so, but I'm not going to accept 15 it in general terms. 16 Q. Let's go to your report, 17 page 34, paragraph 71. And you talk about 18 the different scenarios that the authors 19 chose to test their data for the potential 20 of recall bias. 21 A. Yes. 22 Q. And you choose a 50 percent 23 number to illustrate the potential 24 problems, correct?</p>

<p style="text-align: right;">Page 362</p> <p>1 MS. LEHMAN: Object to form.</p> <p>2 THE WITNESS: So are you</p> <p>3 talking about in paragraph B where</p> <p>4 I say 50 percent --</p> <p>5 BY MR. TISI:</p> <p>6 Q. Correct.</p> <p>7 A. Yeah, I wouldn't say I'm</p> <p>8 choosing that situation, I'm just showing</p> <p>9 an example of --</p> <p>10 Q. Do you believe that a</p> <p>11 50 percent recall bias number is a</p> <p>12 realistic assessment of the problems in</p> <p>13 O'Brien (2024)?</p> <p>14 A. I don't know exactly what is</p> <p>15 a realistic assessment, but I can point you</p> <p>16 to in, again, the differential recall in</p> <p>17 Table A5 is really, yes, it's that big.</p> <p>18 It's doubling the cases in terms of</p> <p>19 missingness at follow-up than what it is in</p> <p>20 controls.</p> <p>21 Q. And you would ignore -- and</p> <p>22 you would ignore the conclusions of O'Brien</p> <p>23 (2023) that says there is not that problem</p> <p>24 of recall bias, right?</p>	<p style="text-align: right;">Page 364</p> <p>1 to miss them, isn't it?</p> <p>2 A. It is. But, again, I believe</p> <p>3 that the reviewers must have just taken</p> <p>4 them at face value.</p> <p>5 Q. Okay.</p> <p>6 A. And I point out in my report</p> <p>7 why this is -- this is one of those, this</p> <p>8 is incredibly misleading. Recall bias</p> <p>9 Scenario 2 in particular is kind of -- it's</p> <p>10 astounding how they present it.</p> <p>11 Q. Well, let's look at one, A,</p> <p>12 and then let's look at B, and then we'll</p> <p>13 look at C.</p> <p>14 A. Okay.</p> <p>15 Q. Scenario A has a positive</p> <p>16 risk hazard ratio even if 50 percent of the</p> <p>17 cases were switched to never use, correct?</p> <p>18 A. No, the point estimate of the</p> <p>19 hazard ratio is 1.07.</p> <p>20 Q. Correct.</p> <p>21 A. It's in Table 1. That .07</p> <p>22 difference is way within sampling</p> <p>23 variability when you look at the width of</p> <p>24 the confidence interval there from 0.81</p>
<p style="text-align: right;">Page 363</p> <p>1 A. I don't know that I'm saying</p> <p>2 that, I mean, ignoring that, this is -- I'm</p> <p>3 just looking at the data that's in this</p> <p>4 paper and that level of differential</p> <p>5 missingness is right there and it's kind of</p> <p>6 obvious.</p> <p>7 Q. Okay. Now, in Table 2, the</p> <p>8 data, tested data, the likelihood of recall</p> <p>9 bias uses several recall bias scenarios,</p> <p>10 all of which pass peer review, right?</p> <p>11 A. That the scenarios pass peer</p> <p>12 review?</p> <p>13 Q. Yes.</p> <p>14 A. The paper went through peer</p> <p>15 review. I don't think there's a concept of</p> <p>16 individual analyses passing peer review.</p> <p>17 Q. Well, if there was a problem</p> <p>18 with these assumptions, wouldn't you have</p> <p>19 expected that not to pass peer review?</p> <p>20 A. I am frankly stunned that the</p> <p>21 peer-review process did not catch this,</p> <p>22 catch the problems in this analysis.</p> <p>23 Q. The recall bias scenarios,</p> <p>24 they're in a big chart on page 9, it's hard</p>	<p style="text-align: right;">Page 365</p> <p>1 to --</p> <p>2 Q. Right.</p> <p>3 A. -- 1.40. And you can see the</p> <p>4 line very clearly crosses 1.0 --</p> <p>5 Q. Right.</p> <p>6 A. -- which is a plausible</p> <p>7 value.</p> <p>8 Q. Okay. Now, let's look at</p> <p>9 25 percent. If they take 25 percent of the</p> <p>10 cases and reassign them to never use,</p> <p>11 there's still a 1.4 relative risk and that</p> <p>12 is statistically significant, correct?</p> <p>13 A. The point estimate is 1.41</p> <p>14 and the confidence interval in that case,</p> <p>15 if all you do is take that 25 percent,</p> <p>16 based on their sort of inappropriate</p> <p>17 approach of just flipping people, then that</p> <p>18 point -- that confidence interval, if you</p> <p>19 accept all of those assumptions, all of the</p> <p>20 steps they did before and the reassignment</p> <p>21 of other magical steps they did, then this</p> <p>22 comes out to be statistically significant,</p> <p>23 but it ignores anything that also might be</p> <p>24 in Scenario 3. So they're basically say</p>

<p style="text-align: right;">Page 366</p> <p>1 the recall bias of Scenario 3 is zero when 2 they come up with that estimate there. 3 Q. Let's talk about them one at 4 a time. Okay? 5 A. Okay. 6 Q. What they're saying here -- 7 A. No, because these things 8 don't exist one at a time -- 9 Q. I understand. We'll talk 10 about it in -- 11 A. -- they're in combination. 12 Q. Doctor, we'll talk about it 13 in total. 14 A. The total here that -- 15 Q. Doctor, Doctor, we'll talk 16 about it in total, I promise you. I've 17 just got to get -- I can only ask one 18 question at one time. So give me a chance 19 to get through the whole thing and I'll ask 20 your opinions because I want to know what 21 they are. Okay? 22 A. Okay. 23 Q. Scenario 1, they say if you 24 take 25 percent of the cases that we</p>	<p style="text-align: right;">Page 368</p> <p>1 Q. -- if they consider recall 2 bias at various levels, right? 3 A. Okay. So I think right now 4 you're specifically referring to the 5 25 percent recall bias level associated 6 with -- 7 Q. For example -- 8 A. -- recall bias Scenario 1, 9 but what I'm saying is that you can't -- 10 this adjustment is conditional on accepting 11 Scenario 4. 12 Q. Right. And they're saying, 13 it states even if Scenario 4 is inflated 14 and we take 25 percent of the cases and 15 throw them into never use, we still have a 16 positive risk ratio of 1.4, right? 17 A. No, because what's in 18 Scenario 4 is more than just recall bias, 19 because as we've discussed, there's the 20 feedback loop. There's the amplification 21 of recall bias that comes from their 22 correction procedure. And so when you 23 think you're correcting 25 percent here, 24 you're not really correcting 25 percent,</p>
<p style="text-align: right;">Page 367</p> <p>1 computed are likely to be cases, and we're 2 going to switch them to never users, we're 3 going to take user and switch them to never 4 users, there's still a positive risk ratio 5 of 40 percent, correct, 41 percent? 6 A. That's point estimate, it 7 ranges from -- well, the risk -- the hazard 8 ratio is 1.41, it's not quite the same 9 thing. And that ranges in a 95 percent 10 confidence interval from 1.06 to 1.87. But 11 this is conditional on you accepting 12 everything they did -- 13 Q. Understood. 14 A. -- up until step four to in 15 their Scenario 4, which I don't -- 16 Q. I understand. We did -- we 17 took care of missingness and data 18 correction. We took care of that. We're 19 now testing it for recall bias, right? 20 They calculated the number they calculated, 21 now they're saying how likely is it that 22 this is a positive association if we 23 consider -- 24 A. What --</p>	<p style="text-align: right;">Page 369</p> <p>1 you're correcting less. 2 Q. Okay. In Scenario B, they 3 say that even if you accept 75 percent of 4 the cases and you reassign them, short-term 5 users or frequent users to never use, you 6 still have an increased risk of 1.34, 7 correct? 8 A. In this case, so the 9 75 percent of infrequent short-term users, 10 and this is really quite, quite incredible, 11 quite bizarre, and that 75 percent, 12 75 percent sounds like a lot, right? But 13 75 percent here is just five people. 14 Q. Okay. 15 A. So if all of this -- you 16 talked about, what did we say, there's 17 50,000 odd people in the study, five people 18 only, you change their assignment, it comes 19 all the way down from 1.82 down to 1.34. 20 Take it to six, you are no longer 21 statistically significant. 22 Q. There were not 50,000 -- 23 A. Take it to seven and then you 24 would be around about 1.1. And totally not</p>

<p style="text-align: right;">Page 370</p> <p>1 statistically significant.</p> <p>2 Q. Doctor, there were not 50,000</p> <p>3 ovarian cancer --</p> <p>4 A. Seven individuals, seven.</p> <p>5 Q. There are not 50,000 ovarian</p> <p>6 cancer cases in the Sister Study, are</p> <p>7 there?</p> <p>8 A. I agree with you. The 50,000</p> <p>9 example was to start with --</p> <p>10 Q. Okay. There's 250 cases --</p> <p>11 A. Right.</p> <p>12 Q. Doctor --</p> <p>13 A. All right. Seven people out</p> <p>14 of 250. You switch their status, your</p> <p>15 results are gone, it's disappeared.</p> <p>16 Q. Let's compare -- let's</p> <p>17 compare apples to apples. That statement</p> <p>18 about 50,000 people compared to seven</p> <p>19 people was misleading, was it not?</p> <p>20 MS. LEHMAN: Object to form.</p> <p>21 Argumentative.</p> <p>22 BY MR. TISI:</p> <p>23 Q. 50,000 -- there were 50,000</p> <p>24 people in the study, only 250 people had</p>	<p style="text-align: right;">Page 372</p> <p>1 infrequent users, you'd have to get almost</p> <p>2 between 15 or 20 percent of those to do</p> <p>3 that as well, right?</p> <p>4 A. If they were the only kind of</p> <p>5 recall bias, which I'm pretty sure the</p> <p>6 authors are not claiming that this is the</p> <p>7 major source of recall bias, I think that</p> <p>8 would be Scenario A. But if this was the</p> <p>9 only source of recall bias, you would need</p> <p>10 a lot to make a really big difference. But</p> <p>11 as we said earlier, these don't come on</p> <p>12 their own, so like the Scenario B recall</p> <p>13 bias, add that onto the Scenario B --</p> <p>14 Scenario C and it's just something -- just</p> <p>15 a few from Scenario B that you flip, and a</p> <p>16 bit of Scenario C, a bit of Scenario A and</p> <p>17 your results just more than disappeared,</p> <p>18 which was doubling inflated in the first --</p> <p>19 no, doubling -- again, perhaps late in the</p> <p>20 day, I shouldn't use that, let's be</p> <p>21 precise, it was an extra inflated hazard</p> <p>22 ratio in the first place that you get from</p> <p>23 Scenario 4 and now with these, you've</p> <p>24 really got these different kinds of recall</p>
<p style="text-align: right;">Page 371</p> <p>1 ovarian cancer, correct?</p> <p>2 A. I agree that I should have</p> <p>3 just used the ovarian cancer number, then</p> <p>4 whatever at this point.</p> <p>5 Q. Thank you.</p> <p>6 A. I'm trying to -- it's late in</p> <p>7 the day --</p> <p>8 Q. I understand, me too.</p> <p>9 A. I will say that still seven</p> <p>10 out of 250 is a very small proportion, such</p> <p>11 that when you're running a sensitivity</p> <p>12 analysis and your result disappears with</p> <p>13 changing as few as a handful of your</p> <p>14 participants. I mean, this is why we do</p> <p>15 sensitivity analysis, we look to see do our</p> <p>16 results stand the test if we just -- how</p> <p>17 much are we relying on our models, our</p> <p>18 assumptions, and so on, because we really</p> <p>19 don't want to make statements that are,</p> <p>20 like, so easily manipulated to disappear.</p> <p>21 Q. And if you look at section --</p> <p>22 if you look in Scenario 3, if they take</p> <p>23 people who are non-cases and kind of test</p> <p>24 them and throw them into the short-term or</p>	<p style="text-align: right;">Page 373</p> <p>1 bias in combination and it wouldn't take</p> <p>2 much to make it disappear --</p> <p>3 Q. So let me --</p> <p>4 A. Just again, my report, my --</p> <p>5 the central statement in my report is that</p> <p>6 they're not showing a reliable association</p> <p>7 between talc use and ovarian cancer and</p> <p>8 this kind of demonstrates that it's not</p> <p>9 reliable. Even if you accepted their</p> <p>10 Scenario 4, you can play with these</p> <p>11 scenarios and as many as they came up with</p> <p>12 that retain a hazard ratio, I can come up</p> <p>13 with a whole new set where the hazard ratio</p> <p>14 becomes statistically insignificant and</p> <p>15 disappears.</p> <p>16 Q. So in the editorial that</p> <p>17 accompanied this, they address that</p> <p>18 question, don't they? Let's go back to</p> <p>19 Exhibit No. 6, which is the Harris, Terry,</p> <p>20 Davis editorial?</p> <p>21 A. I'm going to ask you for</p> <p>22 my -- I understand we're in the middle of</p> <p>23 towards the question and I'm happy to sort</p> <p>24 of answer this, but then if we could have a</p>

<p style="text-align: right;">Page 374</p> <p>1 break again.</p> <p>2 Q. No question, and just to give</p> <p>3 you a sense, I'm kind of -- there's one</p> <p>4 area I want to cover that's separate from</p> <p>5 this, but I want to get through the recall</p> <p>6 bias issue and so if you give me some</p> <p>7 leeway here, I'll give you some leeway as</p> <p>8 well. Okay?</p> <p>9 A. Okay. Then maybe can you</p> <p>10 just give me 15 seconds to get some water,</p> <p>11 because I feel my mouth dry --</p> <p>12 Q. Of course.</p> <p>13 A. Okay.</p> <p>14 Q. Actually, let's take it now.</p> <p>15 I don't mean for you to be uncomfortable</p> <p>16 for sure. I just want to get you to bed.</p> <p>17 A. Okay. Thank you.</p> <p>18 Q. It's late over there.</p> <p>19 A. Yup, much appreciated.</p> <p>20 -----</p> <p>21 (A recess was taken at this time.)</p> <p>22 -----</p> <p>23 BY MR. TISI:</p> <p>24 Q. Dr. Kornak, going to Exhibit</p>	<p style="text-align: right;">Page 376</p> <p>1 risks based upon the misclassification</p> <p>2 scenario provided, this editorial asks that</p> <p>3 the reader do that? Did you do that?</p> <p>4 A. I don't think it asks the</p> <p>5 reader to do that. They say the reader can</p> <p>6 do that if they want to.</p> <p>7 Q. Did you do that?</p> <p>8 A. That would be based on all of</p> <p>9 the assumptions that O'Brien has taken in</p> <p>10 her correction, manipulation, imputation</p> <p>11 approaches --</p> <p>12 Q. Did you do that?</p> <p>13 A. -- before getting to the</p> <p>14 recall bias.</p> <p>15 Q. Did you do that?</p> <p>16 A. I think I just described to</p> <p>17 you examples of that, like, flipping seven</p> <p>18 people would change the result and so</p> <p>19 forth. I think we went through that whole</p> <p>20 thing of when it would versus when it</p> <p>21 wouldn't. Yeah, and again, I'm looking for</p> <p>22 something that will indicate that there's</p> <p>23 reliability in the result.</p> <p>24 Q. Looking at the next page, it</p>
<p style="text-align: right;">Page 375</p> <p>1 No. 6, the fourth paragraph down.</p> <p>2 A. Yes.</p> <p>3 Q. Okay. It says "After</p> <p>4 accounting for potential biases or O'Brien</p> <p>5 et al. report a significant increase in</p> <p>6 ovarian cancer for genital powder use, with</p> <p>7 effect estimates that are in range of</p> <p>8 previous studies."</p> <p>9 Going down to the end, it</p> <p>10 says "While the degree of bias is unknown,</p> <p>11 the reader can make their own assessment</p> <p>12 about the reasonable range of realistic</p> <p>13 risks based upon the misclassification</p> <p>14 scenarios provided. In this paper, even</p> <p>15 with misreporting of the exposure in half</p> <p>16 the cases, a significant increase in</p> <p>17 ovarian cancer risk is still observed,</p> <p>18 adding support to the plausibility of a</p> <p>19 true association between genital powder use</p> <p>20 and ovarian cancer."</p> <p>21 Do you see that?</p> <p>22 A. Yeah, I see that.</p> <p>23 Q. Have you made an assessment</p> <p>24 about the realistic range of realistic</p>	<p style="text-align: right;">Page 377</p> <p>1 says "Given that ovarian and uterine</p> <p>2 cancers are both gynecologic cancers and</p> <p>3 the reported association with one but not</p> <p>4 the other may not be appreciated by the</p> <p>5 general population, one could expect them</p> <p>6 to be similarly affected by recall bias.</p> <p>7 Thus, the lack of association between</p> <p>8 genital use and uterine case provides</p> <p>9 additional report that recall bias does not</p> <p>10 fully explain the genital powder and</p> <p>11 ovarian cancer association."</p> <p>12 Do you agree or disagree</p> <p>13 with that?</p> <p>14 A. I disagree with that.</p> <p>15 Q. Why?</p> <p>16 A. So if you want to go back to</p> <p>17 O'Brien -- no, there's a couple of reasons.</p> <p>18 I mean, in terms of the mechanism for</p> <p>19 recall bias, my understanding is that the</p> <p>20 stories were about -- the reporting was</p> <p>21 about genital talc use and ovarian cancer.</p> <p>22 I don't recall ever seeing anything about</p> <p>23 douching, maybe there was. But that's not</p> <p>24 my main point.</p>

<p style="text-align: right;">Page 378</p> <p>1 My main point here is if you 2 look at -- actually, I have a couple of 3 main points. Let me start with the 4 straightforward one, if you look at row 4 5 of table A5. 6 Q. Uh-huh. 7 A. So I'm just going to the data 8 here, I'm not relying, not ascribing the 9 mechanism or anything, but if we look at 10 the differential recall, again, in the 11 genital talc column, overall 19 percent. 12 You look at uterine cancer, the cases, 13 20 percent. Barely any differential recall 14 there. You look at postmenopausal breast, 15 21 percent. Barely any differential recall 16 there. I mean it's not nothing, but it's 17 small. 18 You look at the 19 premenopausal breast cancer, that's a 20 little bit higher at 27, but it's still 21 very small compared to the difference 22 between 37 and 19. That differential 23 recall is massive. 24 So why -- why -- I gave you</p>	<p style="text-align: right;">Page 380</p> <p>1 again, the main message I wanted to say is, 2 like, the differential recall is there 3 baked in the data, you see it in -- 4 Q. My question is in paragraph 5 number 25, you say that this study is 6 inconsistent with their prior work. If you 7 would go to that page, that paragraph. 8 A. Yeah, I'd say that's a 9 general kind of statement that -- 10 Q. Let's -- 11 A. -- the prior prospective 12 work -- 13 Q. Let's look at them, if you 14 don't mind? 15 A. Oh, sure, yeah. 16 Q. If you would go to the 17 Gonzalez study again. You say Gonzalez 18 finds a hazard ratio of .73. 19 Do you see that? 20 A. I say that they estimate a 21 hazard ratio. 22 Q. That wasn't for lifetime use, 23 was it? 24 A. Sorry?</p>
<p style="text-align: right;">Page 379</p> <p>1 one possibility as to why there's that 2 difference, that the bigger stories were 3 about talc use and ovarian cancer rather 4 than douching, but it's here in the data. 5 The differential recall is clearly there in 6 O'Brien's own data that is much bigger in 7 ovarian cancer than the other types. 8 Q. I'm going to ask you a couple 9 of questions related to your paragraph 10 number -- 11 A. I want to finish with, sorry, 12 it's going to take me a second to just find 13 the third piece that I wanted to -- so, for 14 example, I think Table 2, if we look at 15 uterine cancer, it goes on to the next 16 page. No, it's not that there's no -- the 17 recall bias is definitely not there. As 18 you go from Scenario 1 to Scenario 2, it 19 states that -- but then it does increase 20 with Scenario 3. It's a very small 21 increase with Scenario 4 there. I mean, 22 it's negligible. It goes from .98 to 1.01. 23 So there may be a slight of recall bias. I 24 don't know that it's zero there. But,</p>	<p style="text-align: right;">Page 381</p> <p>1 Q. That wasn't for lifetime use, 2 was it? 3 A. That was for -- I don't know 4 to the extent that -- I mean, the question 5 they asked their participants was whether 6 they used between the ages of 10 to 13 or 7 in the last 12 months. To the extent that 8 that's representative of lifetime use, 9 that's what this hazard ratio represents. 10 Q. They say if you go to the 11 end, the last sentence on page 7, they say 12 on page 7, it says "In this large, 13 prospective study, we did not observe an 14 association between recently talc use and 15 ovarian cancer." Do you see that, not 16 lifetime use? 17 A. Well, the definition includes 18 10 to 13, so I don't know that -- that may 19 or may not be recent for -- 20 Q. Well, they talk about 10 to 21 13, they didn't have a lot of data, it was 22 mostly the year, the year before that they 23 had data. So they talked about recent use, 24 correct?</p>

<p style="text-align: right;">Page 382</p> <p>1 A. I don't recall -- I don't 2 recall them saying that they only have data 3 on the last year, but not on 10 to 13. Can 4 you point me to where that is? 5 Q. Well, in any event, because 6 I'm trying to wrap this up, they talk 7 about -- they talk about that this is an 8 association between recent use and, of 9 course, O'Brien (2025) [sic] talks about 10 lifetime use, right? 11 A. In this paper, they do use 12 the term "recent talc use." In O'Brien 13 (2024), not '25, we're not there yet. In 14 2024, they do say they're examining 15 lifetime use. 16 Q. The next one is O'Brien 17 (2020), that's Exhibit 25 in your book. 18 A. Yes. 19 Q. Okay. In this study, they 20 make clear that looking at women with 21 patent tubes is an important subgroup to 22 look at? 23 A. Okay. Do you want to point 24 me to the section?</p>	<p style="text-align: right;">Page 384</p> <p>1 there is an adjusted hazard ratio of 1.13 2 that goes from 1.01 at the lower end of 3 plausible values through to 1.26. But I 4 would caution in the interpretation of that 5 is if I was working with anybody on a 6 project where their confidence interval 7 went down that low, I would want them to be 8 able to deal with does that reach a 9 clinically significant level. Could it be 10 due to any biases or assumptions or model 11 assumptions or a reverse error results 12 robust to that lower confidence interval 13 that we really want to make the claim that 14 we have a statistically significant result. 15 And, in this case, I know I 16 already was suspicious, this is -- being a 17 combination of studies, you're always 18 subject to publication bias inflating 19 hazard ratios. And then you in addition 20 earlier in this deposition pointed out to 21 me that one of the studies was actually 22 using retrospective information. So then 23 there's recall bias in there. So then I 24 would not want to rely on that 1.01 being</p>
<p style="text-align: right;">Page 383</p> <p>1 Q. Sure. They talk about on 2 page 51, it says on the right-hand side, it 3 says "Because patency is required for there 4 to be a direct physical pathway between the 5 powder application area and the ovaries, we 6 hypothesized a priori that women with 7 patent reproductive tracts would be more 8 susceptible to the effects of powder use in 9 the genital area on ovarian cancer. We 10 therefore conducted analyses restricted to 11 this subgroup. When estimating the effects 12 of duration of powder on ovarian cancer 13 risk, we compared long-term, greater than 14 20 years, and non-long-term users with 15 never users." 16 Do you see that? 17 A. Yes. 18 Q. Okay. And if you look at the 19 data when they looked at women with intact 20 tubes on Table 2, the overall risk ratio 21 was 1.13 with a hazard -- with a confidence 22 interval that does not cross one, correct? 23 A. Table 2? So in the pooled 24 estimate, yes, what you're highlighting</p>	<p style="text-align: right;">Page 385</p> <p>1 genuinely above one. So this is -- 2 Q. But this is in the section 3 where you say that the results of the 2024 4 were inconsistent with the results of her 5 prior studies. We demonstrated that 6 Gonzalez was only looking at recent talc 7 use, correct? And now we're looking at 8 O'Brien (2020), which talks about a 9 statistically significant increased risk in 10 cohort data using prospective data, which 11 in women who did not have hysterectomy, 12 true? 13 A. I think that's not quite 14 true. You already told me that part of 15 this is retrospective -- 16 Q. No, not this part -- 17 A. Well, the consistency should 18 be compared against the Sister Study and if 19 we look at the, you know, across the 20 studies, you can see that the hazard ratios 21 here are -- 22 Q. Doctor -- 23 A. -- far from being 24 statistically significant from one, but</p>

<p style="text-align: right;">Page 386</p> <p>1 this is what I was -- it's my --</p> <p>2 Q. In your report, in your</p> <p>3 report?</p> <p>4 A. -- report that I was writing</p> <p>5 about, it was inconsistent.</p> <p>6 Q. I'm not fussing --</p> <p>7 A. In a hazard ratio estimate of</p> <p>8 1.84 is inconsistent with one at 1.13. In</p> <p>9 fact, it's inconsistent with the whole</p> <p>10 confidence interval by a factor of four.</p> <p>11 Q. You know that --</p> <p>12 A. So --</p> <p>13 Q. You know that Dr. O'Brien</p> <p>14 has said, because you looked at her</p> <p>15 response to the letter to the editor, she</p> <p>16 has said that she thought that the actual</p> <p>17 risk was greater than 1.13, correct?</p> <p>18 A. I don't recall her saying</p> <p>19 that. I don't dispute that she did.</p> <p>20 Q. Okay. And you know that in</p> <p>21 her -- in subsequent publications, she</p> <p>22 agreed that there was a positive</p> <p>23 association, true, even in her 2020 study?</p> <p>24 A. I'm not sure -- I've known</p>	<p style="text-align: right;">Page 388</p> <p>1 bring it up on the screen. Can you go to</p> <p>2 where -- she's one of the authors, she and</p> <p>3 Dr. Wentzensen are one of the authors of</p> <p>4 this paper. It says "In the largest</p> <p>5 prospective study so far, the OC3 found a</p> <p>6 very small positive association between</p> <p>7 genital powder use and ovarian cancer risk</p> <p>8 among all women, 1.08, as well as among</p> <p>9 women with intact uterus and fallopian</p> <p>10 tubes, 1.13."</p> <p>11 Isn't it true, Doctor, when</p> <p>12 they describe the results of 2024 -- I'm</p> <p>13 sorry, 2020, they see a positive</p> <p>14 association in the pooled study of cohorts?</p> <p>15 A. Well, that has a duration of</p> <p>16 1.08 is a point estimate, it's not</p> <p>17 statistically significant that --</p> <p>18 Q. Right, but --</p> <p>19 A. The confidence interval has a</p> <p>20 plausible value of one -- and the</p> <p>21 confidence interval crosses one, it has a</p> <p>22 plausible value of .99 or one.</p> <p>23 Q. Right. And then they say</p> <p>24 taken into context with the ovarian cancer</p>
<p style="text-align: right;">Page 387</p> <p>1 her -- I remember seeing somewhere that</p> <p>2 she's, you know, if we want to go somewhere</p> <p>3 specific, I know you're concerned about</p> <p>4 time.</p> <p>5 Q. Let's do that, exhibit --</p> <p>6 A. But I know she said that, you</p> <p>7 know, that in her response to a statement</p> <p>8 that she isn't -- wasn't ruling out that</p> <p>9 there is a possible positive association --</p> <p>10 I'm not making that claim that it's</p> <p>11 impossible there's a positive association.</p> <p>12 I'm just saying that there's no reliable</p> <p>13 demonstration of a positive association.</p> <p>14 Q. Let's look, this is in a</p> <p>15 section where you're talking about her</p> <p>16 conclusion of a positive association in</p> <p>17 O'Brien (2024) is inconsistent with her</p> <p>18 prior studies. So let's look at Exhibit</p> <p>19 No. 13, if you would. It's an exhibit we</p> <p>20 looked at before and if you go to -- can</p> <p>21 you go to the page, I don't know what</p> <p>22 number it is, it's exhibit -- it's page 13,</p> <p>23 I believe, and this document is not</p> <p>24 paginated, so if you want to try to just</p>	<p style="text-align: right;">Page 389</p> <p>1 with the women with patent tubes, there's a</p> <p>2 positive association consistent with an</p> <p>3 association, true?</p> <p>4 A. So in that case, there's --</p> <p>5 we're referring to the hazard ratio point</p> <p>6 estimate of 1.13 there with a --</p> <p>7 Q. Yes.</p> <p>8 A. -- 5 percent confidence</p> <p>9 interval of 1.01 to 1.26. Again, I just</p> <p>10 would be very cautious about whether or not</p> <p>11 I wanted to say that we have a result here</p> <p>12 given that the lower end is 1.01 --</p> <p>13 Q. And we will --</p> <p>14 A. -- which is entirely subject</p> <p>15 to assumptions. But I also, I'm not sure</p> <p>16 what data goes into this analyses and</p> <p>17 whether there's retrospective components or</p> <p>18 not and the potential for recall bias, so I</p> <p>19 just want to --</p> <p>20 Q. So you don't know?</p> <p>21 A. If you want to take the time</p> <p>22 to walk me through it, I would probably</p> <p>23 give you a better answer.</p> <p>24 Q. I understand, but you don't</p>

<p style="text-align: right;">Page 390</p> <p>1 have an opinion right now? I mean, they 2 are saying, they know their own data and 3 they say there's a positive association 4 particularly in women with patent tubes and 5 that's a positive association, true? 6 A. Yeah, but I think you 7 started -- well, it's one point -- 8 Q. That's what they say? 9 A. As a point estimate, it's a 10 positive association. But in the same way 11 as case-control studies, if there's any 12 recall bias in there that's statistically 13 significant, it's so on the boundary. I 14 explained before, if that happened in a 15 study I was involved in, and that was, we 16 considered that to be a central result of 17 the study, I would -- I would pull all the 18 stops out to do every kind of sensitivity 19 analysis I could and question any potential 20 sources of bias that could be meaning to 21 you to have that marginal -- 22 Q. Of course, you didn't even 23 know about the ovarian -- 24 A. Again, going back to your</p>	<p style="text-align: right;">Page 392</p> <p>1 of .91 to 1.24 and you refer to the 2 appendix S4. 3 Do you see that? 4 A. On the screen at the moment 5 is the paper itself. I'm referring to the 6 appendix. 7 Q. Now, if you go to the 21, if 8 you don't mind, on page 21, because I have 9 that up here. It says this is the chart S4 10 and it says "Association between 11 one-frequency category increase in use of 12 single personal care product, breast, 13 ovarian, uterine cancer using Cox 14 proportional hazards models." 15 Do you see that? 16 A. Okay, I've got the table, 17 yes. 18 Q. And actually if you go to the 19 next page is where you see at the top, you 20 see the number that you pull out, which is 21 1.0. Talc vaginal use, I think you have 22 1.07 with a .94, 1.23. 23 Do you see that? 24 A. Yes.</p>
<p style="text-align: right;">Page 391</p> <p>1 earlier question, you were relating to 2 whether or not it was consistent with 3 O'Brien (2024). The O'Brien (2024) 4 preferred analysis, they're talking about a 5 hazard ratio of 1.84. They're not talking 6 about -- 7 Q. But they both showed a 8 positive association? 9 A. Sorry? 10 Q. We can talk about the 11 strength of the association, but they both 12 showed a positive association, right? 13 A. But that's not what I mean by 14 consistency. If you're going to have 15 consistent results, you know, it's like 16 saying I have five apples or 5,000 apples 17 and saying that's the same thing, it's not 18 the same thing. 19 Q. The next one is Chang, you 20 refer to the Chang study. Let's talk about 21 that briefly. It's Exhibit No. 22 in your 22 book. And your report says that the 23 overall hazard ratio for talc and ovarian 24 cancer was 1.06 with a confidence interval</p>	<p style="text-align: right;">Page 393</p> <p>1 Q. Okay. But that's in 2 relationship to what they call -- that's 3 not the overall risk ratio, that is a 4 one-frequency category increase, correct? 5 A. Yes. 6 Q. Okay. And what is a 7 one-frequency category increase? 8 A. I have to remind myself of 9 that. 10 Q. Well, let me see if I can 11 help you, Doctor, because I know it's 12 getting late. Let me see that if I can 13 help you. Go to page 14 of the article in 14 the conclusion. Do you see that? Did you 15 actually read this paper? 16 A. I don't think I read it 17 completely. 18 Q. Okay. They say -- 19 A. I assumed I looked at the 20 paper. 21 Q. Well, did the lawyers point 22 out to you the 1.06 confidence or relative 23 risk and say that was the overall hazard 24 ratio seen in this paper?</p>

<p style="text-align: right;">Page 394</p> <p>1 A. No.</p> <p>2 MS. LEHMAN: Object to form.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Well, it says "Although the</p> <p>5 observed effects of a one-frequency level</p> <p>6 increase was modest in magnitude, the</p> <p>7 impact would be more substantial when</p> <p>8 comparing the most frequent users with</p> <p>9 never users. For example, an 8 percent</p> <p>10 higher hazard of postmenopausal breast</p> <p>11 cancer for one-frequency level increase in</p> <p>12 the beauty mixture could translate to</p> <p>13 approximately a 36 percent higher hazard</p> <p>14 ratio for the most frequent users compared</p> <p>15 to never users."</p> <p>16 Do you see that?</p> <p>17 A. I do see that.</p> <p>18 Q. Okay. So if ours is -- you</p> <p>19 talk about a 1.06, here is a one point --</p> <p>20 they're using an 8 percent ratio and</p> <p>21 they're talking about if you add the</p> <p>22 numbers together or multiply them the way</p> <p>23 you should, if it was more frequent user,</p> <p>24 that number would be close to 30 percent,</p>	<p style="text-align: right;">Page 396</p> <p>1 making some big assumption, it was that I</p> <p>2 didn't --</p> <p>3 Q. Well, your report --</p> <p>4 A. -- read the totality of this</p> <p>5 particular paper.</p> <p>6 Q. In your report, just to be</p> <p>7 clear, your report says Chang uses data</p> <p>8 from the Ovarian Cancer Institute, 2003 to</p> <p>9 2020, the estimate and HR summarizes the</p> <p>10 association between genital talc and</p> <p>11 ovarian cancer is 1.06. That's what you</p> <p>12 assumed and that's not true, is it?</p> <p>13 A. I said that's not completely</p> <p>14 untrue, it's a 1.06 association.</p> <p>15 Q. It's one-level increase and</p> <p>16 for more frequent users in this data, it's</p> <p>17 approximately 30 percent, correct?</p> <p>18 MS. LEHMAN: Object to form.</p> <p>19 THE WITNESS: Well, okay.</p> <p>20 Like I said, there was quite a bit</p> <p>21 to unpack there. That 36 percent</p> <p>22 doesn't come with a confidence</p> <p>23 interval. That confidence interval</p> <p>24 could be -- because there would be</p>
<p style="text-align: right;">Page 395</p> <p>1 right, for talc users?</p> <p>2 A. Okay. So there's quite a bit</p> <p>3 to unpack there. I still would like to</p> <p>4 know what the definition is of a</p> <p>5 one-frequency level change.</p> <p>6 Q. You relied on this paper, you</p> <p>7 don't know?</p> <p>8 A. No, I don't recall.</p> <p>9 Q. Okay. And so --</p> <p>10 A. I haven't read it completely,</p> <p>11 if I may have misread what was meant in the</p> <p>12 table. I found the results of the table, I</p> <p>13 reported it, but I obviously missed --</p> <p>14 Q. You assumed that that was the</p> <p>15 overall risk ratio, didn't you?</p> <p>16 MS. LEHMAN: Object to form.</p> <p>17 BY MR. TISI:</p> <p>18 Q. You assumed that was the</p> <p>19 overall hazard ratio, didn't you?</p> <p>20 A. I don't recall exactly what I</p> <p>21 was thinking, but I would not say that I</p> <p>22 didn't -- I may have, I may have looked at</p> <p>23 that and thought it was, whether I was --</p> <p>24 the reason I was mistaken wasn't that I was</p>	<p style="text-align: right;">Page 397</p> <p>1 less data go into that, it could be</p> <p>2 much wider. An 8 percent, of</p> <p>3 course, not everybody who is a user</p> <p>4 is in that category. So on</p> <p>5 average, users versus nonusers</p> <p>6 would likely be somewhere in</p> <p>7 between those estimates. I don't</p> <p>8 know where in between those</p> <p>9 estimates.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. But you, actually,</p> <p>12 misread the --</p> <p>13 MS. LEHMAN: Hold on. Hold</p> <p>14 on. He wasn't done. He's still</p> <p>15 answering.</p> <p>16 THE WITNESS: So all I'm</p> <p>17 saying is there's a lot of</p> <p>18 uncertainty. I acknowledge that in</p> <p>19 my report it would have been better</p> <p>20 to say that that hazard ratio was</p> <p>21 associated with a one-level</p> <p>22 increase.</p> <p>23 BY MR. TISI:</p> <p>24 Q. And could be higher, right?</p>

<p style="text-align: right;">Page 398</p> <p>1 And could be as much as 30 percent, which 2 is consistent with all the other studies 3 that were out there, right? 4 MS. LEHMAN: Object to form. 5 THE WITNESS: No, I mean, 6 it's -- it might be consistent with 7 many case-control studies out there 8 to be around 30 percent. But 9 certainly not consistent with 10 cohort studies and never not with 11 prospective cohort studies. 12 - - - - - 13 (Stenographer clarification.) 14 - - - - - 15 THE WITNESS: And not 16 consistent with cohort studies and 17 certainly not consistent with 18 prospective cohort studies. I 19 think that's my best guess at what 20 I said. 21 BY MR. TISI: 22 Q. Can you -- 23 A. So, it's actually midnight 24 here, I mean I don't know how much</p>	<p style="text-align: right;">Page 400</p> <p>1 unreliable -- 2 Q. Their study from 2024 -- I'm 3 sorry, let me rephrase the question. You 4 disagree with the NIH scientists who 5 published in O'Brien (2024) a study that 6 appeared in the peer-reviewed literature 7 regarding the likelihood of recall bias 8 affecting the Sister Study cohort, you 9 disagree with them, true? 10 A. I would rephrase it and say 11 that I have, as I've expressed in my 12 report, I have -- I disagree with 13 assumptions and approaches taken in O'Brien 14 (2024) and that I have problems with their 15 manipulation, correction, imputation 16 approach to -- 17 Q. And you think that the peer 18 reviewers, you think the peer reviewers who 19 looked at this paper didn't understand or 20 missed the obvious flaws in this study, 21 true? 22 MS. LEHMAN: Object to form. 23 Asked and answered. 24 THE WITNESS: They missed,</p>
<p style="text-align: right;">Page 399</p> <p>1 longer -- 2 Q. I'm going to wrap it up. 3 I've got about four or five questions and 4 if you'll answer them directly, I'll be 5 done. 6 A. I can't guarantee that, but 7 I'll do my best. 8 Q. All right. We agreed that 9 before May 20, 2024, when you met with the 10 J&J lawyers, you had never looked at the 11 issue of talc and ovarian cancer, correct? 12 MS. LEHMAN: Object to form. 13 THE WITNESS: If I saw it in a 14 news article somewhere, I may have 15 noted it in my brain, but I did not 16 research it and look into it. 17 BY MR. TISI: 18 Q. And in your report, you 19 disagree and call unreliable NIH scientists 20 who not only published O'Brien (2024) in a 21 peer-reviewed journal, but multiple studies 22 over the past almost ten years from the 23 Sister Study, correct? 24 A. I do not call NIH scientists</p>	<p style="text-align: right;">Page 401</p> <p>1 didn't understand, didn't dig into 2 reviews, I don't know. I can't 3 comment on what was in their minds. 4 What I can comment on is that those 5 flaws exist in the paper, these 6 problems exist in the paper, and 7 the paper did get through peer 8 review, so. 9 BY MR. TISI: 10 Q. And you disagree with 11 scientists like Harris and Terry who were 12 invited to do an editorial, who thought 13 that recall bias does not explain the 14 genital powder and ovarian cancer 15 association, correct? 16 MS. LEHMAN: Objection. Asked 17 and answered. 18 THE WITNESS: I disagree with 19 their conclusion about the O'Brien 20 (2024) paper. I disagree with 21 their general conclusions. I 22 believe that the paper does not 23 reliably demonstrate an association 24 between talc use and ovarian</p>

<p style="text-align: right;">Page 402</p> <p>1 cancer.</p> <p>2 BY MR. TISI:</p> <p>3 Q. And you disagree with the</p> <p>4 American Society of Clinical Oncology who</p> <p>5 said that this was a robust and good</p> <p>6 analysis of the Sister data incorporating</p> <p>7 rigorous adjustments for bias that may have</p> <p>8 affected earlier studies? You disagree</p> <p>9 with them as well, correct?</p> <p>10 MS. LEHMAN: Objection. Asked</p> <p>11 and answered.</p> <p>12 THE WITNESS: I disagree with</p> <p>13 their statement. I'm not, like,</p> <p>14 looking to disagree with them as</p> <p>15 individuals. I'm not just making</p> <p>16 up disagreements. My report was</p> <p>17 about the paper. I explicitly</p> <p>18 state the problems of the paper. I</p> <p>19 explicitly state why there are</p> <p>20 problems. I don't see anywhere</p> <p>21 where in any of those editorials</p> <p>22 that you describe that they go into</p> <p>23 those details in any way. I don't</p> <p>24 see anywhere they do that.</p>	<p style="text-align: right;">Page 404</p> <p>1 lawyers, correct?</p> <p>2 MS. LEHMAN: Object to form.</p> <p>3 THE WITNESS: The only place I</p> <p>4 have written down my opinions is in</p> <p>5 the report.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Which you started three days</p> <p>8 after meeting Johnson & Johnson's lawyers,</p> <p>9 true?</p> <p>10 MS. LEHMAN: Object to form.</p> <p>11 THE WITNESS: I believe</p> <p>12 that's -- that after, you know,</p> <p>13 many hours of reviewing the paper,</p> <p>14 I started drafting, yeah, within</p> <p>15 three days.</p> <p>16 BY MR. TISI:</p> <p>17 Q. And you never sought and do</p> <p>18 not intend to seek to publish your findings</p> <p>19 or your conclusions outside the courtroom,</p> <p>20 true?</p> <p>21 A. Yeah, I have no intention of</p> <p>22 doing that.</p> <p>23 Q. Okay. And the opinions that</p> <p>24 you've given in this case, you have been</p>
<p style="text-align: right;">Page 403</p> <p>1 BY MR. TISI:</p> <p>2 Q. And you disagree with the</p> <p>3 NIH, which said the bias analysis was</p> <p>4 rigorous and the study provides compelling</p> <p>5 evidence of genital talc use is associated</p> <p>6 with an increased risk of ovarian cancer,</p> <p>7 you disagree with them as well, right?</p> <p>8 MS. LEHMAN: Object to form.</p> <p>9 Asked and answered.</p> <p>10 THE WITNESS: It's not about I</p> <p>11 disagree with their conclusion,</p> <p>12 but, again, there's no particular</p> <p>13 aspect where they've gone into the</p> <p>14 details of what I've argued with</p> <p>15 they're saying there's something I</p> <p>16 said that's incorrect. They don't</p> <p>17 go into the details. So there's</p> <p>18 kind of --</p> <p>19 BY MR. TISI:</p> <p>20 Q. And the only -- and the only</p> <p>21 place that you have ever expressed your</p> <p>22 opinion was in your report that you</p> <p>23 authored, that you started writing three</p> <p>24 days after receiving the study from the</p>	<p style="text-align: right;">Page 405</p> <p>1 paid and will be paid over \$100,000, true?</p> <p>2 MS. LEHMAN: Object to form.</p> <p>3 THE WITNESS: For writing my</p> <p>4 report, for reading materials, for</p> <p>5 preparing for deposition, for all</p> <p>6 of the time I've spent in putting</p> <p>7 together my independent assessment</p> <p>8 of O'Brien (2024) and related</p> <p>9 materials, yes, the total comes to</p> <p>10 over 100,000.</p> <p>11 BY MR. TISI:</p> <p>12 Q. And you were located in this</p> <p>13 case through a headhunter called</p> <p>14 Cornerstone, because you had been involved</p> <p>15 in other cases going back almost ten years</p> <p>16 as a litigation expert for law firms, true?</p> <p>17 MS. LEHMAN: Object to form.</p> <p>18 Asked and answered. And you're now</p> <p>19 at seven hours and one minute, so</p> <p>20 this is the last question.</p> <p>21 THE WITNESS: Cornerstone is a</p> <p>22 company. I don't know that I would</p> <p>23 describe them as headhunters. And,</p> <p>24 like I say, and I've said before, I</p>

<p style="text-align: right;">Page 406</p> <p>1 don't know the details of the</p> <p>2 operation of the company. They did</p> <p>3 approach me. I don't have any</p> <p>4 relationship with them that goes</p> <p>5 back ten years. They contacted me</p> <p>6 and asked me about the case and</p> <p>7 whether I would be willing to take</p> <p>8 a look at O'Brien (2024) and</p> <p>9 consider providing an independent</p> <p>10 assessment.</p> <p>11 BY MR. TISI:</p> <p>12 Q. And be an expert in</p> <p>13 litigation?</p> <p>14 MS. LEHMAN: You don't need to</p> <p>15 answer that. Counsel's time is</p> <p>16 over.</p> <p>17 MR. TISI: I disagree. You're</p> <p>18 going to instruct him not to answer</p> <p>19 that question?</p> <p>20 MS. LEHMAN: Counsel, you have</p> <p>21 asked this question.</p> <p>22 MR. TISI: You're going to</p> <p>23 instruct him --</p> <p>24 MS. LEHMAN: I'm telling you,</p>	<p style="text-align: right;">Page 408</p> <p>1 took the same approach.</p> <p>2 BY MS. LEHMAN:</p> <p>3 Q. Okay. And have you used the</p> <p>4 same biostatistical tools that you use in</p> <p>5 your everyday work and that you teach to</p> <p>6 your students?</p> <p>7 MR. TISI: Objection.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MS. LEHMAN:</p> <p>10 Q. I'm sorry, Dr. Kornak, I</p> <p>11 think you broke up for me. What was your</p> <p>12 answer?</p> <p>13 A. Yes.</p> <p>14 Q. And do you hold the opinions</p> <p>15 that are set out in your report to a</p> <p>16 reasonable degree of scientific certainty?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Have you used multiple</p> <p>19 imputation in your publications, in the</p> <p>20 studies that have been published?</p> <p>21 A. Yes, I'm sure I have, but I</p> <p>22 would struggle right here right now to say</p> <p>23 which ones.</p> <p>24 Q. Okay. You talked to counsel</p>
<p style="text-align: right;">Page 407</p> <p>1 your time is up.</p> <p>2 MR. TISI: Because I disagree.</p> <p>3 So are you going to tell him not to</p> <p>4 answer that question?</p> <p>5 MS. LEHMAN: I am. I am.</p> <p>6 MR. TISI: Okay. Have a good</p> <p>7 day, Dr. Kornak. Good evening.</p> <p>8 BY MS. LEHMAN:</p> <p>9 Q. All right. Dr. Kornak, I</p> <p>10 have a few questions for you. Dr. Kornak,</p> <p>11 are your opinions in this case fully set</p> <p>12 out in your report?</p> <p>13 A. Yes.</p> <p>14 Q. And are the opinions that you</p> <p>15 express in your report, have you done and</p> <p>16 performed the same types of analysis that</p> <p>17 you do in your biostatistical work outside</p> <p>18 of the courtroom?</p> <p>19 MR. TISI: Objection.</p> <p>20 THE WITNESS: These are the</p> <p>21 same kind of approach I take to</p> <p>22 reviewing papers that I'm involved</p> <p>23 in as a coauthor. It's the same if</p> <p>24 I'm asked to review a paper. I</p>	<p style="text-align: right;">Page 409</p> <p>1 earlier about something that I think you</p> <p>2 called Bayesian analysis; is that correct?</p> <p>3 A. Uh-huh.</p> <p>4 Q. Okay. And what is -- is</p> <p>5 there a relationship between Bayesian</p> <p>6 analysis and imputation?</p> <p>7 A. Yes, there is. Kind of like</p> <p>8 a Bayesian analysis involves having -- you</p> <p>9 can build in observed variables and</p> <p>10 unobserved variables. And the unobserved</p> <p>11 variables would be, you consider missing</p> <p>12 data to be unobserved variables within a</p> <p>13 Bayesian analysis. So they are very much</p> <p>14 related.</p> <p>15 Q. Okay. And is Bayesian</p> <p>16 analysis an approach of statistical</p> <p>17 inference?</p> <p>18 MR. TISI: Objection.</p> <p>19 THE WITNESS: It's an approach</p> <p>20 of statistical modeling and</p> <p>21 inference.</p> <p>22 BY MS. LEHMAN:</p> <p>23 Q. Okay. Based on your</p> <p>24 education, your training, the work that</p>

<p style="text-align: right;">Page 410</p> <p>1 you've done as a biostatistician in your 2 years as a professor, does O'Brien (2024) 3 show an association between genital talc 4 use and ovarian cancer? 5 MR. TISI: Objection. 6 THE WITNESS: No, they do not 7 show an association. 8 BY MS. LEHMAN: 9 Q. Okay. Based on your 10 education, your training, your work as a 11 biostatistician, your years as a 12 professor -- actually, strike that. Let me 13 ask a different question. 14 Does O'Brien (2024) 15 specifically state that their results do 16 not establish causality and do not 17 implicate any specific cancer-inducing 18 agent? 19 A. Yes. 20 Q. All right. Is recall bias 21 real or is that only a theoretical 22 possibility? 23 MR. TISI: Objection. Asked 24 and answered.</p>	<p style="text-align: right;">Page 412</p> <p>1 A. I would need to remind myself 2 of it exactly where that is. 3 Q. Sure. No problem. And I 4 think you have O'Brien (2023) with you. 5 It's in the notebook at tab 16. And if you 6 look at page 7 at the last paragraph above 7 the word "discussion." 8 A. Yes. 9 Q. Okay. 10 A. Yes, so it talks about the 11 trend being reversed among those with 12 intervening ovarian cancer diagnosis with 13 28 percent self-reporting genital talc use 14 at enrollment and 33 percent reporting 15 genital talc at the follow-up 16 questionnaire. 17 Q. And then to move on -- 18 A. This was the only subgroup 19 for which the proportion of users increased 20 between enrollment and follow-up. 21 Q. And did they say that that 22 could indicate recall bias -- 23 A. And it could indicate, yeah, 24 it could indicate recall bias, i.e.,</p>
<p style="text-align: right;">Page 411</p> <p>1 THE WITNESS: It exists. 2 BY MS. LEHMAN: 3 Q. All right. And does O'Brien 4 (2024) specifically state that the 5 participants reporting talc use could be 6 recalling products that contain talc, 7 cornstarch, or a mixture and women may have 8 used different products at different times? 9 A. Yes. 10 Q. Does O'Brien (2023) 11 acknowledge that when talking about -- that 12 there can be some evidence of recall bias 13 of genital talc use among ovarian cancer 14 survivors? 15 MR. TISI: Objection. 16 THE WITNESS: Yes. 17 BY MS. LEHMAN: 18 Q. And, in fact, did O'Brien 19 (2023) call out the subgroup of ovarian 20 cancer survivors as a group for which there 21 was a proportion in which the -- those 22 reporting talc use increased from 23 enrollment and that was the only subgroup 24 for which that was true?</p>	<p style="text-align: right;">Page 413</p> <p>1 overreporting of talc use among those with 2 a history of ovarian cancer. 3 Q. We looked at O'Brien (2024) a 4 lot. And what -- the question I have there 5 is does the O'Brien (2024) article contain 6 a disclaimer that the work was funded by 7 the National Institutes of Health, but that 8 the National Institutes of Health had no 9 role in the design, conduct, or 10 interpretation of the study? 11 A. Yes, that's there at the end. 12 Q. Okay. Now, you were asked a 13 couple of questions about the Ovarian 14 Cancer Cohort Consortium. That was Exhibit 15 No. 13. 16 A. Yes. 17 Q. On your materials considered 18 list includes an article published in the 19 Journal of National Cancer Institute titled 20 "Analgesic use and ovarian cancer risk: 21 And analysis in the Ovarian Cancer Cohort 22 Consortium," correct? 23 A. I need to double check that 24 one. That is not one that --</p>

<p style="text-align: right;">Page 414</p> <p>1 MR. TISI: Do you have a copy 2 of that, Kate? 3 MS. LEHMAN: Yeah, I can just 4 show it. Do you want our copy of 5 the article or -- 6 THE WITNESS: It's -- 7 MS. LEHMAN: I'm not going to 8 ask him about the article, 9 otherwise, I would happily send it 10 to you. It's just on the materials 11 considered list, Dr. Kornak. 12 THE WITNESS: It's on 13 Exhibit 23, yes, I have the list 14 here and, what was the title again? 15 ----- 16 (Trabert Article marked 17 Kornak Exhibit 23 for 18 identification.) 19 ----- 20 BY MS. LEHMAN: 21 Q. It should be "Analgesic use 22 and ovarian cancer risk: An analysis of 23 the Ovarian Cancer Cohort Consortium." 24 MR. TISI: What was the year?</p>	<p style="text-align: right;">Page 416</p> <p>1 your memory, Dr. Kornak, that the IARC 2 press release stated that a causal role for 3 talc could not be fully established? 4 A. Yes, that's correct. 5 MR. TISI: Objection. 6 BY MS. LEHMAN: 7 Q. Okay. And when you were 8 asked about O'Brien (2020), is it correct 9 that O'Brien (2020) states, "However, these 10 findings may be affected by recall bias and 11 a recent surge in talc-related lawsuits and 12 media coverage has increased this 13 possibility"? 14 MR. TISI: Objection. 15 THE WITNESS: Yes. 16 MS. LEHMAN: Okay. All right. 17 Dr. Kornak, those are all the 18 questions I have at this time. 19 Thank you. 20 MR. TISI: Have a good night. 21 MS. LEHMAN: Robin, he will 22 read and sign. 23 MR. TISI: Robin, I'm going to 24 request a rough --</p>
<p style="text-align: right;">Page 415</p> <p>1 MS. LEHMAN: 2019. It's the 2 article by Trabert. 3 THE WITNESS: I got it, yeah. 4 BY MR. TISI: 5 Q. And is that on your materials 6 considered list? 7 A. Yes. 8 Q. Okay. And so it would be 9 inaccurate to say the first time you ever 10 heard of the Ovarian Cancer Cohort 11 Consortium was during this deposition, 12 correct? 13 A. It would be inaccurate, yes. 14 Q. Okay. You were asked some 15 questions about -- 16 MR. TISI: How much longer, 17 Kate? I mean, in all 18 seriousness -- 19 MS. LEHMAN: I have, like, 20 three minutes. 21 BY MS. LEHMAN: 22 Q. Okay. You were asked some 23 questions about the IARC press release and 24 you were shown the Lancet article and is it</p>	<p style="text-align: right;">Page 417</p> <p>1 MS. LEHMAN: I guess my 2 question is when do you think 3 you'll be able to send the rough? 4 Can you flip it over tonight? 5 THE STENOGRAPHER: I will try. 6 ----- 7 (Whereupon, the deposition 8 was concluded at 6:19 p.m.) 9 ----- 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

Page 418	Page 420																																																															
<p>1 CERTIFICATION</p> <p>2</p> <p>3</p> <p>4 I HEREBY CERTIFY that the proceedings and</p> <p>5 evidence are contained fully and accurately in the</p> <p>6 stenographic notes taken by me upon the foregoing</p> <p>7 matter on July 8, 2024, and that this is a correct</p> <p>8 transcript of same.</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14 <i>Robin L. Clark</i></p> <p>15 Robin L. Clark</p> <p>16 Registered Professional Reporter</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21 (The foregoing certification of this</p> <p>22 transcript does not apply to any reproduction of the</p> <p>23 same by any means unless under the direct control</p> <p>24 and/or supervision of the certifying reporter.)</p>	<p>1 -----</p> <p>2 ERRATA</p> <p>3 -----</p> <table><thead><tr><th>4 PAGE</th><th>LINE</th><th>CHANGE</th></tr></thead><tbody><tr><td>5</td><td>---</td><td>---</td></tr><tr><td>6</td><td>---</td><td>---</td></tr><tr><td>7</td><td>---</td><td>---</td></tr><tr><td>8</td><td>---</td><td>---</td></tr><tr><td>9</td><td>---</td><td>---</td></tr><tr><td>10</td><td>---</td><td>---</td></tr><tr><td>11</td><td>---</td><td>---</td></tr><tr><td>12</td><td>---</td><td>---</td></tr><tr><td>13</td><td>---</td><td>---</td></tr><tr><td>14</td><td>---</td><td>---</td></tr><tr><td>15</td><td>---</td><td>---</td></tr><tr><td>16</td><td>---</td><td>---</td></tr><tr><td>17</td><td>---</td><td>---</td></tr><tr><td>18</td><td>---</td><td>---</td></tr><tr><td>19</td><td>---</td><td>---</td></tr><tr><td>20</td><td>---</td><td>---</td></tr><tr><td>21</td><td>---</td><td>---</td></tr><tr><td>22</td><td>---</td><td>---</td></tr><tr><td>23</td><td>---</td><td>---</td></tr><tr><td>24</td><td>---</td><td>---</td></tr></tbody></table>	4 PAGE	LINE	CHANGE	5	---	---	6	---	---	7	---	---	8	---	---	9	---	---	10	---	---	11	---	---	12	---	---	13	---	---	14	---	---	15	---	---	16	---	---	17	---	---	18	---	---	19	---	---	20	---	---	21	---	---	22	---	---	23	---	---	24	---	---
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<p>Page 419</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over carefully</p> <p>4 and make any necessary corrections.</p> <p>5 You should state the reason in the appropriate</p> <p>6 space on the errata sheet for any corrections</p> <p>7 that are made.</p> <p>8 After doing so, please sign the errata</p> <p>9 sheet and date it.</p> <p>10 You are signing same subject to the</p> <p>11 changes you have noted on the errata sheet,</p> <p>12 which will be attached to your deposition.</p> <p>13 It is imperative that you return the</p> <p>14 original errata sheet to the deposing attorney</p> <p>15 within thirty (30) days of receipt of the deposition</p> <p>16 transcript by you. If you fail to do so, the</p> <p>17 deposition transcript may be deemed to be accurate</p> <p>18 and may be used in court.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>Page 421</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, JOHN KORNAK, PhD, do hereby</p> <p>4 certify that I have read the foregoing pages</p> <p>5 and that the same is a correct</p> <p>6 transcription of the answers given by me to</p> <p>7 the questions therein propounded, except for</p> <p>8 the corrections or changes in form or</p> <p>9 substance, if any, noted in the attached</p> <p>10 Errata Sheet.</p> <table><thead><tr><th>11 DATE</th><th>SIGNATURE</th></tr></thead><tbody><tr><td>12</td><td>Subscribed and sworn to before me this</td></tr><tr><td>13</td><td>day of ,</td></tr><tr><td>14</td><td>2024.</td></tr><tr><td>15</td><td>My commission expires:</td></tr><tr><td>16</td><td></td></tr><tr><td>17</td><td></td></tr><tr><td>18</td><td></td></tr><tr><td>19</td><td></td></tr><tr><td>20</td><td>Notary Public</td></tr><tr><td>21</td><td></td></tr><tr><td>22</td><td></td></tr><tr><td>23</td><td></td></tr><tr><td>24</td><td></td></tr></tbody></table>	11 DATE	SIGNATURE	12	Subscribed and sworn to before me this	13	day of ,	14	2024.	15	My commission expires:	16		17		18		19		20	Notary Public	21		22		23		24																																				
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[& - 13]

Page 1

&	1.06 367:10	347:19 369:19	114 5:1
& 1:3 2:12,18	391:24 393:22	1.84 252:7	115 5:6
3:3 9:2 35:6	394:19 396:14	386:8	117 5:10
37:9,20 38:6,13	1.06. 396:11	1.84. 261:7	1180 2:19
38:22 39:16,18	1.07 282:19	391:5	12 4:21 130:15
39:19,23 40:2	392:22	1.87. 367:10	130:24 155:22
41:4 107:20	1.07. 364:19	1.88 236:3	210:14 211:13
109:20 110:9	1.08 388:8,16	10 4:9,16,18	221:13 246:10
110:13 159:19	1.1. 369:24	25:4,7,18 125:7	249:3,5,14,21
198:3 200:12	1.13 383:21	125:18 210:8	266:16 274:9
236:14 404:8	384:1 386:17	210:13 213:19	283:19 381:7
0	389:6	216:10 219:24	125 4:18
0.76 156:13	1.13. 386:8	220:2 221:12	129 4:17
0.81 364:24	388:10	225:1 235:18	13 4:22 36:19
07 364:21	1.17 280:24	246:9 263:14	112:14 136:10
08002 3:4	282:2	263:23 270:14	136:17 210:8
1	1.23. 392:22	271:1,9 272:3	210:14 211:10
1 4:9 10:12,16	1.24 392:1	274:9,16,18	213:19 216:10
10:20 16:14	1.26. 384:3	278:10 283:19	219:24 220:2
23:7 24:12	389:9	287:19 293:16	221:12 225:2
26:19 50:19	1.3 137:23	297:15 304:6	239:23 243:16
155:23 166:24	138:10	304:24 381:6	246:9 260:5,5
183:15 282:19	1.33 157:14	381:18,20	261:9,15
294:15 295:23	1.34 369:6	382:3	263:15,24
307:7 364:21	1.34. 369:19	100 47:23 73:3	270:14 271:9
366:23 368:8	1.36 234:23	73:5,10 90:8,17	272:3 274:9,16
379:18	1.38. 156:14	235:13 237:11	274:18 278:10
1.0 365:4	1.39 235:21	100,000 405:1	283:19 287:19
1.0. 392:21	1.4 365:11	405:10	293:16,23
1.01 384:2,24	368:16	101 252:17	294:2 297:15
389:9,12	1.40. 365:3	10:04 1:13	304:6,24
1.01. 379:22	1.41 365:13	11 4:19 25:19	353:18 354:1
1.02 156:11	367:8	133:8,18	381:6,18,21
282:23	1.81 347:3,15	112 5:3	382:3 387:19
	1.82 233:15	113 5:9	387:22 413:15
	234:8,22 250:3		

[130 - 2024]

Page 2

<p>130 4:21 133 4:19 136 4:22 138 214:20,23 14 4:23 6:6 30:18 60:21 149:16,24 168:4,10 211:18 213:6 213:15 216:5,6 218:17 262:6 271:8 393:13 149 4:23 15 11:18,19 63:6 108:16 109:8,16 111:20 154:1 158:4 372:2 374:10 16 5:1 114:18 114:22 212:24 216:22 241:12 247:5 412:5 16-2738 1:4 165 5:8 17 5:2 204:11 214:13 215:11 173 4:12 18 5:3 53:18 54:11 112:9,17 210:24 264:4 264:15 266:2,2 182 4:13 1825 2:13 19 4:11 266:9 354:7 378:11</p>	<p>378:22 191 4:14 193 4:15 1983 131:17 320:3 332:16 1995 131:7 1997 131:18</p> <hr/> <p>2</p> <hr/> <p>2 4:10 13:24 24:16,16 25:2 29:4,11 30:16 64:3 68:1 83:18 129:10 189:17 189:19 211:1 230:23 235:13 269:9 276:1 278:24 279:12 279:21,24,24 290:21 295:17 295:23 296:11 342:4 347:3 349:2,7 358:22 359:3 363:7 364:9 379:14 379:18 383:20 383:23 2.01 235:20 2.08 236:8 2.43 234:24 2.91 235:21 20 5:4 16:6 20:4 21:10 23:15 26:7,13 27:15 43:16 44:24 45:11 49:1</p>	<p>50:14 53:8 75:1 80:23 90:18 118:1,8,14 132:15 164:2 200:22 211:10 212:12 213:21 216:13 225:4 227:2 271:1,8 272:6 274:7,19 315:19,24 372:2 378:13 383:14 399:9 20,000 75:13 2000 134:22 20006 2:14 2003 111:22 112:13 126:10 156:8 396:8 2005 131:9 2007 131:10 134:22 2009 127:17 135:3 2010 146:14 2013 4:15 135:5 193:20 2015 36:19 37:10,15 2016 37:15,20 38:14 112:6,13 113:8 118:14 287:3 2017 37:20 38:6 156:9 217:3 2019 217:3 415:1</p>	<p>202-759-7648 2:14 2020 5:9 70:6 113:12,16 117:4 142:13 142:23 144:3 154:18,21 156:7 158:12 158:14,14 159:9 203:5 382:17 385:8 386:23 388:13 396:9 416:8,9 2022 30:20,23 31:12 33:11 2023 5:1 30:20 30:24 114:16 114:21 166:12 203:5 214:4,9 215:22 216:22 218:17 220:15 225:22 226:23 238:21,23 239:24 254:22 255:12 256:19 259:17,20,23 260:17 263:20 352:7 353:7 362:23 411:10 411:19 412:4 2024 1:7 4:14 4:16 9:12 10:4 10:13 11:1,13 11:18,20,21 16:5,6,18 20:4 20:5 21:10,18</p>
--	--	--	--

[2024 - 36104]

Page 3

22:14,17,22	382:13,14	25 5:9 113:13	3
23:8,16,21	385:3 387:17	113:17 116:18	3 3:4 4:11 19:18
24:22 26:6,7,13	388:12 391:3,3	116:21,22,23	19:24 26:5 45:7
27:15 30:21	399:9,20 400:2	156:18,19	126:5 133:22
31:6 49:1 52:22	400:5,14	157:4 309:21	189:12,20
55:5 57:23 58:2	401:20 405:8	338:16 365:9,9	235:17 250:18
64:4 71:15 90:3	406:8 410:2,14	365:15 366:24	279:14 295:18
90:18 92:20,24	411:4 413:3,5	368:5,14,23,24	295:23 332:6
107:23 108:8	418:7 421:14	380:5 382:13	337:2,6 365:24
108:10 111:14	2025 382:9	382:17	366:1 371:22
116:10 118:1	20th 28:2 49:4	250 370:10,14	379:20
120:9 121:4	52:23,24 53:21	370:24 371:10	3.34 282:2
130:6,12 132:3	54:7,9,14 55:5	25b 156:5,6	30 164:2 211:10
141:1 145:9,11	55:6 61:21 90:3	25th 51:6	225:4 274:7
148:21 149:6	21 5:5 45:11	26 5:10 45:11	276:5 394:24
149:12 155:2,7	221:7 227:4	117:2,11	396:17 398:1,8
155:23 156:16	298:23 299:9	26th 51:7	419:15
157:6,15,16	299:23 378:15	27 45:11 378:20	30309 2:19
158:19 159:10	392:7,8	27th 51:7	31 254:5
161:14,18	215 5:2	28 23:8 24:8	310 3:4
163:14 166:12	218 2:8	45:12 50:14	315 5:4
166:13,14	21st 53:12	153:24 154:2	316 2:3
167:24 173:15	22 5:6 45:11	158:4 264:5	32 95:5 146:7
188:2 191:15	111:23 115:19	266:2 412:13	227:5 314:22
195:7 196:1,3	115:21 116:1	28th 28:4,4	334:3
201:24 203:6	391:21	51:7	32502-5996 2:4
213:15 215:21	22nd 49:24	29 4:10 22:22	33 412:14
228:24 230:5	50:7 53:12,22	45:12 68:2 95:6	34 221:7 361:17
244:1 246:3	53:23 54:14	146:7 227:2	35 210:18 211:2
248:13,16,17	55:7,12,13	252:15 275:23	211:7 219:12
249:13,18	23 5:7 244:18	299 5:5	219:19 221:5
255:1 260:4,17	414:13,17	2a 153:6	36 394:13
262:7 265:7	23rd 51:5,9	2b 153:6	396:21
312:7 333:8	52:16 53:3,9		36104 2:9
351:10 354:4	24 5:8 9:3		
358:15 362:13	165:18,24		

[37 - 90]

Page 4

<p>37 266:9 378:22 38 214:21 264:7 265:2 266:18 267:3,12,13,18 267:22,23 268:4,13,16 39 213:22 216:13 272:6</p>	<p>44 309:7,16 45 161:2 49 211:19</p>	<p>6,416 219:8 225:16 6,438 220:5,6 225:10,15 6.6 112:22 113:2 600 2:3 6:19 417:8</p>	<p>111:13 116:10 128:19,21 132:6 213:15 216:4 230:5 260:4 264:18 279:7 309:22 313:10 394:9 394:20 397:2 418:7 8,002 219:8 220:7 8,525 193:9 80 196:15 231:15 237:10 80/20 273:23 800-898-2034 2:9 82 233:17 234:10 850-435-7176 2:4 856-317-7188 3:5 87 242:15,18 243:2,9 256:24 258:5 263:22 353:18</p>
4	5	7	
<p>4 4:12 24:16,16 25:2 134:21 173:13 174:1 183:4 213:2,3 230:4,11,12 233:1 234:20 266:7 269:11 290:20 294:17 295:23 313:8 321:24 347:12 347:19 354:6 367:15 368:11 368:13,18 372:23 373:10 378:4 379:21 4.44 282:13 40 367:5 404-572-2716 2:20 406 6:6 407 4:4 41 367:5 414 5:7 42 316:17 334:2 336:11,15</p>	<p>5,000 391:16 5/23 53:8 50 56:12 73:3 212:12 361:13 361:22 362:4 362:11 364:16 50,000 12:6 16:22 17:1 72:2 72:9,16 111:18 111:19 183:9 183:19 345:3 369:17,22 370:2,5,8,18,23 370:23 50,400 72:17 51 383:2 54 264:5,8 265:2 266:2 338:15</p>	<p>7 4:3,15 193:7 193:21 204:11 230:23 269:8 279:18,21 381:11,12 412:6 7,314 137:24 70,000 73:11 700 2:13 73:9 71 361:17 73 211:19 293:17,24 294:2 380:18 74 75:2 211:2 211:16 292:23 293:10,14,17 75 210:18 211:2 219:13 369:3,9 369:11,12,13 77 30:18 36:20 79 157:13</p>	
	6	8	9
	<p>6 4:14 190:6 191:16 226:24 241:9,14 242:14 373:19 375:1</p>	<p>8 1:7 4:16 9:19 10:5,14,16 11:13 13:23 60:21 61:3</p>	<p>9 4:17 128:22 129:2 247:1,4 363:24 9,855 193:9 90 196:16 231:15 243:12 244:20 256:22</p>

[908 - actually]

Page 5

908 418:13	167:1 310:10	account 153:11	actual 85:1
91 392:1	abstract 14:12	154:22 238:1	155:19 202:21
92 282:13	abstracts 41:18	327:17	212:15 342:1
93 154:4	academia 78:8	accounting	386:16
94 392:22	162:3	137:20 330:9	actually 7:24
95 156:12	academic 17:17	330:13,14,14	15:9 16:21
157:12 367:9	49:12 58:13	375:4	28:24 29:4 36:4
98 379:22	60:10 68:23	accrued 260:8	39:5 40:16,17
99 388:22	74:17 78:11	261:18	44:2 48:3 49:5
a	79:12,19 87:12	accurate	49:23 50:15
a.m. 1:13	90:12,19 97:7	419:17	51:8 53:20
a1 250:18	98:16 99:8,9	accurately	58:23 60:6
a2 179:8,11	104:4 109:18	83:21 245:13	68:22 91:12
198:11 248:24	110:3 173:7	340:16 418:5	94:1 106:11,11
249:3,4 250:9	232:18	accusing	116:7 120:14
250:14,17,19	academically	302:24 303:4,4	128:19 130:14
261:1 282:23	64:10	acknowledge	132:14 139:6
283:4,5 298:14	academics	197:10 234:24	150:9 153:20
a5 265:6 278:17	70:20	240:11,15	158:12 159:7
278:22 354:6	accept 20:14	242:2 261:3	163:21 169:6,9
362:17 378:5	139:7 180:8	274:22 348:17	173:11 175:5
aalen 319:4	353:10 361:14	351:22 358:5	176:4 177:9
ability 35:2	365:19 369:3	397:18 411:11	178:11 180:3,9
170:17	accepted	acknowledged	189:1 190:5,8
able 31:3	162:12,12,18	348:6	190:10 191:20
140:22 159:21	162:21 163:8	acknowledges	192:21 193:3
162:8 226:17	166:12 225:15	197:12	194:2 196:2
266:4 288:22	232:18 282:6	acknowledging	199:8 207:3,15
311:23 361:10	373:9	197:15 329:10	208:8,17 209:6
384:8 417:3	accepting	347:23	209:14 210:7
above 131:14	367:11 368:10	acknowledg...	212:5 214:2,24
342:11 360:9	accompanied	421:1	217:1 224:9
385:1 412:6	190:10 195:24	acquired	225:20 227:11
absolutely	199:14 373:17	298:18 359:13	237:22,24
109:23 165:3	accompanies	activity 186:19	238:5 240:9
	195:10		242:2,12,13

[actually - ahead]

Page 6

244:6 245:3 278:8 280:9 281:14 284:21 285:5,8 299:14 302:15 303:11 307:24 311:12 312:9 314:18 315:15 325:21 340:13,17 346:17 347:21 354:3,5 374:14 378:2 384:21 392:18 393:15 397:11 398:23 410:12 add 238:11 372:13 394:21 added 84:3 138:24 266:16 adding 339:16 339:17 359:10 375:18 addition 73:6 116:13 169:5 170:8 343:8 384:19 additional 63:21 83:7 144:20 263:7 342:10 359:19 377:9 address 60:24 61:6 96:2 184:3 190:7 195:12 195:21 228:2 232:8 317:18	329:11 373:17 addressed 95:17,21 228:24 addressing 16:5 adequately 235:7 adjust 187:19 adjusted 384:1 adjusting 14:19 186:13 187:15 187:16 adjustment 368:10 adjustments 25:11 175:15 178:17 187:21 188:20 189:7 283:4 351:17 402:7 administrative 28:23 29:21 33:18 46:7,15 admit 162:2 advantage 222:11 223:14 advice 135:23 advocate 256:4 affect 330:23 affected 106:3 175:16 178:18 188:21 221:21 237:20 353:20 360:9 377:6 402:8 416:10	affecting 400:8 affects 269:4 age 211:18,22 213:6,18 219:11 221:7,7 227:3 263:14 272:3 274:8,16 274:18,19 279:9 293:10 293:17,23 aged 211:2 agency 149:17 150:21 agent 410:18 ages 210:13 211:10 213:21 215:18 216:10 219:24 225:1,4 227:2 263:23 270:14 271:8 272:3,5 283:19 294:2,8 381:6 ago 11:18 89:19 140:10 agree 12:15 13:11 14:24 15:3 23:12 26:9 42:17 43:8 85:7 87:7 125:24 150:15 153:3 156:23 159:13 159:24 160:2 163:11,17,18 169:19 173:12 174:5 177:10 184:23 188:18	189:3 201:24 206:24 208:4 220:12 227:16 227:24 234:16 240:1 244:17 248:8 251:13 256:11 259:14 259:15 260:2 260:15 262:2 262:14,22 272:12 281:3 283:12 284:12 295:11,13 296:9 298:24 300:1,11,16 301:6,19 306:18,19 309:14 326:1,4 328:2,5 331:11 370:8 371:2 377:12 agreed 7:3 164:14 222:3 283:12 386:22 399:8 agreement 220:15,16 263:17 353:18 agrees 220:2 ahead 8:15 44:13 74:7 106:7 127:1 128:23 297:10 315:18 330:22 332:13
--	--	--	---

[air - answered]

Page 7

air 231:24	231:19 261:17	294:1,8,9	answer 6:4
al 195:11 375:5	295:24 300:7,8	298:10,14	31:21 67:7 83:5
alabama 2:9	332:8 359:8	305:4,22 306:8	84:17 89:11
alarm 298:8	363:16 383:10	307:3,4,11,15	90:14,17 101:9
align 353:16,17	389:16	307:20 309:3	102:10 109:2,6
aligned 277:9	analysis 9:7	318:6,6 320:5,5	110:6 123:9
allegations	13:4,17 20:24	323:19 325:17	124:12,15
73:22	25:15 42:13	325:17 327:12	147:2,10,11,20
allen 2:7	64:2,13 66:2,13	327:21 329:8	148:18 155:18
allison 299:4	67:6,12,20,24	330:8 331:5	157:5 164:7
allow 245:5	75:3 76:1 77:1	332:5 333:7	170:3 191:2
allowed 22:4	80:18 106:2	337:22 342:12	199:9 201:4
amazed 106:23	124:3,20	342:15 343:7	206:10 207:20
133:2 141:4	134:13 141:8	344:23 347:2,7	209:8 212:15
amazing 107:2	141:16 142:14	348:3 354:18	220:19 221:7
american 127:9	148:1 149:5	358:17,18	221:11 222:6,8
127:14 131:6	157:7 163:12	359:15 361:9	223:10,12
131:10 182:3	163:22 164:9	363:22 371:12	224:10 226:5
182:23 183:4	164:15,17	371:15 390:19	245:6 255:13
194:10 402:4	174:22 175:11	391:4 402:6	256:20 257:6
amount 58:17	175:23 176:6	403:3 407:16	271:5 272:8,13
71:12 72:12	176:21 178:6	409:2,6,8,13,16	272:22 276:20
243:23 256:1	178:22 179:6,8	413:21 414:22	285:23,23
353:21	185:3,19 193:9	analytical	286:4,5,19,21
amplification	195:18 197:11	148:12	286:23 289:1
368:20	198:2,5,10,12	analyze 86:12	297:1,9,11,20
amplify 334:20	229:3,6 230:7	134:9 138:12	298:15 327:4
amplifying	230:13,24	140:23 242:13	333:16 337:5
329:23 331:9	233:2,7,12,14	305:22 356:21	342:18,19
analgesic	254:10 260:8	analyzed 86:10	373:24 389:23
413:20 414:21	260:22 261:1	175:17	399:4 406:15
analyses 41:11	269:4 272:20	analyzes	406:18 407:4
41:20 56:17,22	275:24 276:6	287:20 360:24	408:12
57:13 105:22	276:10 277:11	analyzing	answered 15:19
157:7 180:4	278:4,4 283:7	84:19 141:3	21:20 23:19
189:8,15	286:1 288:22	229:13	27:3 35:10

[answered - argue]

Page 8

50:21 61:17 62:9,12 63:17 64:6,24 67:9 68:16 71:7 77:4 77:23 79:4 98:23 101:17 102:11 108:2 109:11 120:22 124:23 161:22 191:22 199:24 200:17 201:14 219:20 221:1 222:19 232:11 236:19 244:13 244:14,20 270:18 286:9 292:20 302:7 304:5,23 306:2 317:6 320:22 346:3 349:24 400:23 401:17 402:11 403:9 405:18 410:24 answering 206:13 219:21 257:16 258:16 258:19 297:14 298:15 326:21 397:15 answers 243:11 243:17 263:10 421:5 anybody 48:6 80:5 108:9 110:8 198:23 199:18 201:8	236:21 351:7 384:5 anymore 341:14 anyway 118:4 apologies 247:16 apologize 107:18 167:10 170:3 208:2 appear 115:12 116:11 148:6 170:9 236:16 appearances 2:1 3:1 appeared 11:14 11:17 400:6 appearing 7:2 appears 45:16 45:18 125:3 163:15,17 194:22 264:17 appendix 68:1 68:8 124:8 392:2,6 apples 370:17 370:17 391:16 391:16 applicable 139:23 application 126:14 128:8 383:5 applications 87:18 128:13	applied 100:23 101:1 107:14 108:4 316:14 316:14 applies 281:11 apply 272:19 355:6 418:22 appointed 135:4 appreciate 180:16,18,19 180:21 181:4,6 182:1 265:9 324:5 appreciated 374:19 377:4 approach 26:17 49:11 74:21 94:18 99:8 100:10 106:4 147:22 186:3 238:12 304:16 312:5 321:7 327:14 365:17 400:16 406:3 407:21 408:1 409:16,19 approached 17:2 approaches 107:13 123:20 149:1,4 301:12 306:13 339:24 376:11 400:13 approaching 101:20	appropriate 48:13,14 62:4 63:19 68:19 71:11 74:1 97:1 98:5 100:12 148:16,23 335:4 419:5 appropriately 86:12 313:3 appropriateness 95:15 147:7 215:16 291:16 approval 169:7 170:11 approved 218:9 328:12 approximately 394:13 396:17 arbitrary 67:13 67:15 234:14 238:9 295:12 295:14 296:10 296:12 area 52:10 84:23 85:8,11 88:21 236:22 238:8 374:4 383:5,9 areas 52:6 84:12 87:15 89:2 136:1 139:24 argue 263:8 269:14 271:6 302:9 326:5 341:10 361:4
--	---	--	--

[argued - associated]

Page 9

argued 288:9 351:6 403:14 arguing 256:15 256:18 341:11 argumentative 61:17 256:8 345:5 346:3 370:21 article 4:12,14 5:5,7 90:2,12 90:19 104:21 163:15,16,18 164:10 165:2,6 165:17,18 168:15 169:6 170:9 171:19 171:23 172:4,5 173:24 183:20 186:9 190:10 191:15 193:4,7 195:10 230:6 230:23 238:21 238:23 256:19 299:8 312:7 319:18 322:15 322:15,21 324:13 325:15 334:23 342:24 393:13 399:14 413:5,18 414:5 414:8,16 415:2 415:24 articles 89:13 90:9 94:24 146:5,19 148:11 184:14	203:4 artificial 175:2 358:11 artificially 269:17 asbestos 151:24 152:1,18,19 ascertain 208:22 231:21 asco 4:13 182:17 183:8 183:16,19 184:1 186:9 ascribe 198:6 231:11 ascribing 378:8 ashcraft 2:12 ashcraftlaw.c... 2:15 aside 69:17 asked 15:19 21:19 22:16 23:19 27:2 35:10 37:2,4 42:6,7 44:4 47:148:8 50:21 61:17 62:11 63:17 64:6,18 64:21,24 67:9 68:16 71:6 77:4 77:22 79:3 83:1 98:22 101:17 108:1 109:10 120:22 124:23 133:6 142:17 143:5 144:5,12	145:8 147:3,17 148:4 150:10 151:2,13,14 152:22 161:9 161:12,21 184:9 199:24 200:16 201:13 209:21 210:6 221:18,23 222:4 223:3,6 232:11 236:19 248:20 263:6 283:18 284:3 285:11 297:8 302:6 317:5 320:22 345:16 346:3 349:24 381:5 400:23 401:16 402:10 403:9 405:18 406:6,21 407:24 410:23 413:12 415:14 415:22 416:8 asking 32:18 42:23,24 60:12 63:3 65:3 70:24 78:15 93:3 95:11,23 96:2,4 106:15,16 123:6 152:8 205:12 206:14 225:20 226:1 227:20 228:14 234:16,17 251:11 257:11	257:15,17 267:11 284:7 287:19 294:11 296:5 345:20 356:11 asks 217:9 221:22 222:2,3 270:14 287:18 294:16 376:2,4 aspect 81:2 175:22 176:5 178:20 333:5 403:13 aspects 52:1 77:1 218:4 344:18 assess 175:23 176:7 178:22 245:13 353:13 assessment 55:18 362:12 362:15 375:11 375:23 405:7 406:10 assessments 360:12 assign 276:8 295:14,19 assigned 169:14 assignment 369:18 associate 162:6 165:13 167:5 associated 13:7 14:2 57:6 122:11 145:11
--	--	--	---

[associated - authors]

Page 10

173:18 186:11	388:6,14 389:2	273:19 359:17	70:14 71:3,10
188:14 203:12	389:3 390:3,5	363:18 365:19	71:18 73:23
206:4,19	390:10 391:8	371:18 376:9	79:18 80:10
208:16 212:17	391:11,12	384:10,11	95:16 101:10
250:2 359:2	392:10 396:10	389:15 400:13	106:8 108:19
368:5 397:21	396:14 401:15	astounding	110:24 115:7
403:5	401:23 410:3,7	364:10	115:12 116:11
association	associations	atlanta 2:19	117:15 123:16
14:11,18 15:15	154:5 158:6	attached	141:1 149:10
24:19 25:10	189:9 359:5	419:12 421:8	151:21,21
55:24 56:1	assume 12:20	attacked 338:9	159:11 160:19
116:16 124:21	120:1 183:20	attempt 93:12	160:24 161:1
131:7 154:19	184:10,21	attention	162:14,15
154:24 155:6,8	227:23 264:6	172:23	166:19 167:14
155:24 156:10	264:24 280:4	attorney	170:10 176:21
156:17 157:19	281:8,17,24	419:14	177:13 179:14
158:15 175:13	291:22 295:4	attribution	179:16 180:19
178:15 182:3	296:10 305:1	316:19	192:12,18,20
183:7 186:15	assumed 24:5	austria 1:13 8:1	193:17 195:23
194:11,17,24	42:21,24 78:19	author 59:19	196:10 202:19
195:14 197:4	98:18 266:15	59:22,24 60:23	215:21 228:23
203:17 204:13	274:4 280:15	61:5 62:8,18	229:2 237:4
204:16,24	393:19 395:14	63:8 113:9,23	238:6 241:4
205:23,24	395:18 396:12	130:6 136:12	259:15,16
208:6 209:11	assumes 280:1	194:16,22	264:22,24
240:23 250:4	assuming	199:17 232:7	266:17 267:12
252:10 260:12	271:19 272:23	authored	269:18 275:15
260:14 261:10	280:22	403:23	276:18 277:17
261:22,23	assumption	authority	277:20 287:2,7
318:21 332:20	99:1 271:14	334:12,23	290:19 291:13
349:17 359:18	303:8 305:17	authors 14:9	295:18 297:4
367:22 373:6	305:20 306:9	15:12,14 24:18	302:24 309:8
375:19 377:3,7	326:11 335:3,8	25:8,12 58:22	312:7 316:5
377:11 381:14	335:21 396:1	59:12 60:2,12	319:16 328:18
382:8 386:23	assumptions	66:2,19 68:11	333:22,23
387:9,11,13,16	25:14 177:22	69:16 70:3,3,7	338:11 351:10

[authors - believe]

Page 11

361:18 372:6 388:2,3 available 28:22 33:17 163:9 343:20 average 210:17 227:3 397:5 avoids 157:8 209:1 award 127:17 128:1 131:8,9 awarded 131:7 135:3 171:2 awards 128:4 aware 53:15 55:14 110:7 140:7 142:7 196:24 201:18 236:12 252:24 awful 307:6	227:15 239:24 242:13 248:1 254:2 259:8 279:23 282:22 311:6 313:10 321:22,23 322:14 332:6 335:14 373:18 377:16 390:24 405:15 406:5 background 84:4 194:5 backing 188:7 bad 57:16 116:8 217:23 328:3 358:4 bake 311:5 baked 310:19 310:21 380:3 baking 304:20 329:22 bar 55:23 56:3 56:5 341:19,20 barely 378:13 378:15 based 25:10 29:24 45:19 104:15 130:4 159:3 252:13 267:4 270:12 278:9 292:22 292:24 293:10 298:11 303:16 307:12 322:10 326:6 331:15 365:16 375:13	376:1,8 409:23 410:9 baseline 67:24 119:2 228:11 275:24 276:6 276:10 277:11 281:13 290:2,8 290:14,16 293:15 294:9 297:13 304:11 304:15 basic 326:11 basically 33:24 35:1,2 106:19 130:8 281:13 304:4 305:10 307:12 316:13 339:24 341:2,5 349:14 353:11 354:10 357:15 365:24 basis 184:8 267:6,13,24 268:1 321:14 321:15 bathroom 81:17 bayes 146:12 bayesian 94:5,9 95:7 146:8 148:1 409:2,5,8 409:13,15 baylen 2:3 bear 89:14 beasley 2:7	beasleyallen.... 2:10 beat 341:20 beauty 394:12 bed 374:16 began 356:5 beginning 31:12 53:2 241:15 253:3 260:6 309:18 begun 65:15 352:19 behalf 40:24 48:9 86:24 194:10,16 195:1 belief 188:1 believe 21:11 32:3 41:2 62:8 91:3 92:6 95:24 118:2 130:4 132:20 134:8 135:15 140:3 140:23 144:3 146:5,16 167:14,18,18 174:17 178:2,4 197:23 215:7 218:12,23 298:14 305:2 314:7 317:7 321:8,20 324:17 362:10 364:2 387:23 401:22 404:11
b			
b 4:6 94:10 362:3 364:12 369:2 372:12 372:13,15 back 10:10 33:7 36:5,16 39:21 45:6 48:24 95:5 146:2 158:2,3 162:14,17 167:23 181:2 186:7 195:4 210:16,20 213:14 214:6,9 215:15 216:4			

[bells - biostatistical]

Page 12

bells 298:8	230:7,13,24	350:2,12 351:1	bibliography
benefits 105:19	233:2 235:1	351:12,18,21	48:3
best 162:3	237:3,20,23	352:3,15,22	big 224:3 309:5
163:8 185:1,6	238:11,20,23	353:1,14,21,24	341:4 353:8,21
185:16 186:3	239:16 240:2,5	358:1,3,5,6,16	358:9 362:17
327:11 398:19	240:6,8 241:7	358:17,18	363:24 372:10
399:7	243:11,19,23	359:15,20	396:1
better 288:8	244:10 251:8	360:10 361:20	bigger 254:12
301:13 308:9	251:10,14,17	362:11,24	379:2,6
341:12 357:14	251:23 252:20	363:9,9,23	biggest 358:6
358:4 389:23	252:22 253:16	364:8 366:1	billing 4:11
397:19	254:21 255:1,6	367:19 368:2,5	19:6,19,23 26:5
beyond 30:3	255:22 260:10	368:8,18,21	27:21 49:1
87:22 152:5,24	261:3,20 262:3	372:5,7,9,13	binary 343:15
172:19 222:17	262:19,20	373:1 374:6	binder 9:22
303:9 338:18	278:4 282:17	375:10 376:14	10:11,14 19:19
344:23	282:21 284:1	377:6,9,19	24:12 125:8
bharris 3:5	288:15 292:16	379:17,23	166:6
bias 9:7 13:3,5	292:17 304:17	384:18,23	bio 4:17,18,20
13:14,17 14:3	305:5 310:18	389:18 390:12	4:21 125:17
14:19 15:16	310:21 318:23	390:20 400:7	129:1 130:23
20:6 64:2 67:16	319:12 326:9	401:13 402:7	133:18
86:20 87:6 98:2	326:18 327:5	403:3 410:20	biography
114:16 132:22	327:14,17,18	411:12 412:22	125:9 130:4,16
144:21,22	327:24 328:3,3	412:24 416:10	130:16 131:5
157:9 163:12	328:6,6,7,8,14	biased 301:12	134:20 139:5
163:22 164:8	328:16,19,24	331:23 333:18	biology 130:18
164:15 174:23	329:8,11,17,17	335:22,23	biomarkers
175:23 176:6	329:18,21	biases 24:21	134:3 137:19
176:20 177:19	330:1,8 331:12	175:15 186:14	biostatistic
178:17,21	331:19 333:19	187:16 188:21	80:17 101:24
179:7 189:15	334:10 336:1,8	283:3 298:19	biostatistical
195:13,18,21	340:12,20,22	310:6 318:20	16:19 75:24
197:11,11	347:1,2,7,9,24	336:6 357:13	84:10 85:12
218:2 221:21	348:4,13,18,21	375:4 384:10	104:15 107:1
223:8,8 229:2	349:3,7,16,21		130:8 134:19

[biostatistical - call]

Page 13

135:23 136:7 160:11 165:15 167:22 407:17 408:4 biostatistician 7:21 84:14,18 85:14,18 86:7 87:4 98:3 104:17 114:11 132:12 139:22 179:15 410:1 410:11 biostatisticians 46:8 biostatistics 34:10 130:18 131:16,18,22 132:15 133:1 187:17 bit 14:15 19:16 103:12 112:12 164:1 176:14 237:15 238:14 244:15 262:6 264:18 315:18 339:1,5 341:20 372:16,16 378:20 395:2 396:20 bizarre 268:3 337:16,19 369:11 black 105:15 blame 165:12 166:7	blanking 46:2 blinded 169:13 blindly 300:14 355:6 blow 261:16,17 299:17 313:16 board 338:20 bode 141:1 body 85:3 92:16 book 105:2,8 112:9 113:13 115:20 116:18 153:21,22 165:19 335:10 382:17 391:22 boone 37:20 39:18 bottom 166:10 176:13 194:12 233:20 249:7 264:22,23 bounced 244:14 boundary 104:22 105:15 390:13 box 8:3,8,9 9:20 13:24 bracket 282:2 bracketing 282:8 brain 229:23 399:15 branch 125:11 126:8 129:12	130:19 131:18 131:22 132:15 133:10 brandy 3:3 break 81:18 83:10 145:14 145:19 146:3 149:9 184:12 199:7 202:3 258:13,23,24 323:24 324:1,3 374:1 breaking 81:4 81:10 145:20 184:22 breast 87:18 88:5,11,18 92:4 129:15,19 140:2 250:5 314:5 359:2,10 378:14,19 392:12 394:10 brief 175:4 briefly 7:6 391:21 bring 11:5 115:20 177:19 189:14 388:1 bringing 150:13 brings 203:20 282:17,20,21 broad 263:2 263:8 broke 69:5 408:11	broken 171:12 brought 10:12 11:1 46:24 205:22 bucket 205:15 build 304:18 409:9 building 335:24 340:2 bunch 294:18 business 17:21 18:8 54:24
c			
c 309:18 364:13 372:14,16 418:1,1 calculate 327:22 329:9 330:10 calculated 267:12,21,22 348:12 367:20 367:20 calculating 328:22 calculations 283:9 call 9:11 13:13 20:17 60:6 66:20 75:3 110:11 144:14 160:8 164:5 169:11 170:14 234:20 277:9 281:6 329:19			

[call - case]

Page 14

347:6,8 349:8 393:2 399:19 399:24 411:19 called 9:4 11:22 18:4 41:10,24 42:13 99:16 158:22 229:2 405:13 409:2 calling 163:22 351:5 calls 45:12 campus 3:4 cancer 13:7 14:2 24:21 25:12 55:21 56:2 57:7,21 87:18 88:5,12 88:18,21,22 89:1,1,2,8,11 89:20 90:3,14 90:21 91:5,12 91:24 92:4,5,13 112:2 116:15 117:17 118:8 122:12 129:15 133:11,23 134:1,10 135:17 137:10 137:16,18,20 138:1 139:17 140:2,8,18 142:9 149:18 150:8,18,21 156:8,11 158:16 173:19 175:14,19	176:11 178:16 179:2 183:7,10 186:12 188:15 192:23 193:8 194:6,10,17 195:16 196:23 197:5 203:13 203:18 204:2 204:14,17 205:1,14 207:2 208:7,16 209:12 212:18 233:17,21 234:10 235:19 237:9,12 250:3 250:5,6 251:4 252:7,15 253:4 253:7 260:12 261:22 262:11 264:9 265:3 266:10,14 267:7,15,24 279:15 308:18 309:9,24 310:5 313:21,24 314:4,5,6,6,14 316:6 322:3,8 333:24 334:5 334:16,20 337:10 338:10 347:17 359:10 359:14,19 370:3,6 371:1,3 373:7 375:6,17 375:20 377:11 377:21 378:12	378:19 379:3,7 379:15 381:15 383:9,12 388:7 388:24 391:24 392:13 394:11 396:8,11 399:11 401:14 402:1 403:6 410:4,17 411:13,20 412:12 413:2 413:14,19,20 413:21 414:22 414:23 415:10 cancers 9:6 115:19 129:19 135:10 140:4 359:7,9 377:2,2 capable 205:19 206:3 capture 212:19 213:20 216:11 225:2 227:13 227:19 272:4 277:5 capturing 221:20 carcinogen 151:24 152:2 152:18,20 carcinogenic 4:24 149:22 care 3:6 9:5 115:18 175:14 175:20 176:8 178:15,23	183:9 195:14 213:17 216:8 224:23 359:6 367:17,18 392:12 career 173:7 careers 121:13 121:19 careful 194:19 198:12,12 272:17 310:17 357:13 carefully 246:2 263:16 325:5 419:3 carlson 37:14 39:22 40:5 carried 301:2 306:12 carries 255:5 carry 255:3 case 16:11 24:6 30:13,22 31:11 32:7 33:16,16 33:21 34:19,19 34:22 35:7 37:1 37:7 38:2,24 40:4,16 41:9,12 41:23 42:5,19 43:2,15 44:4,24 56:10,18,19 57:19 70:6 77:19 80:1,6,22 84:6 85:16 87:5 89:18 90:5,24 95:19 97:5
---	---	--	--

[case - check]

Page 15

143:1,8,9 154:7 158:8,21 184:20 185:23 186:1 206:16 207:1 225:21 232:21 255:9 255:10 291:14 295:5 300:8 305:22 306:7 307:4,10,15,19 331:4 332:5 337:24 338:8 338:13 351:9 360:11 361:11 365:14 369:8 377:8 384:15 389:4 390:11 398:7 404:24 405:13 406:6 407:11 cases 12:3 28:22 43:9 193:9 223:10 250:21 252:15 253:4 254:7,8,9 254:13,13,15 256:1 258:11 264:9 265:3 266:10,14 268:15 269:4 278:7 279:16 279:22 298:7 300:6 308:21 310:23 311:4 318:6 337:10 337:17,18	353:20 354:9 354:10 361:3 361:14 362:18 364:17 365:10 366:24 367:1 368:14 369:4 370:6,10 371:23 375:16 378:12 405:15 caspers 37:14 39:22 40:6 catch 69:1 363:21,22 categories 269:22 275:2 282:3 289:24 292:22 categorizations 270:8 categorize 12:1 54:17 253:19 category 270:11,11 273:4 278:8 281:16 296:11 296:13 347:3 392:11 393:4,7 397:4 causal 416:2 causality 410:16 causation 55:19 56:3 205:22 cause 340:7,12 340:15,19,22	caused 57:6 causes 55:20 57:6,21 caution 31:15 39:13 384:4 cautious 31:19 389:10 caveat 333:1 caveats 236:5 301:22 center 209:13 central 87:19 163:14 373:5 390:16 certain 28:12 71:12 108:4 128:17 247:10 259:24 262:3 306:19 344:17 certainly 20:14 21:22 53:15 59:4 74:19 87:16 105:3 133:5 139:24 140:16 153:3 231:13 265:15 306:21 326:4 339:14 346:19 361:7 398:9,17 certainty 43:17 47:24 408:16 certification 418:21 certify 418:4 421:3	certifying 418:24 cetera 88:7 chafe 302:23 305:14 chain 96:12 chance 366:18 chang 5:6 115:19,24 391:19,20 396:7 change 71:19 164:4 286:22 308:24 369:18 376:18 395:5 420:4 changed 163:4 changes 186:18 419:11 421:7 changing 153:17 269:17 330:19 371:13 characterizati... 281:4 characterize 76:12 charge 345:11 charged 72:1 chart 230:22 363:24 392:9 charts 136:2 265:17 check 10:15 12:19 59:21,23 106:2 132:9 147:13 148:6,8
--	--	---	---

[check - colleagues]

Page 16

210:21 246:16 413:23 checking 215:6 cherry 3:4 chief 126:8 choices 67:13 choose 81:8 96:24 268:13 361:8,22 choosing 362:8 chose 231:15 233:7 266:18 266:24 267:2,2 267:23 268:1 268:15,16 361:19 chosen 309:18 chris 69:5 81:14,14 christopher 2:3 chronic 125:11 126:6 129:6 circular 309:7 309:22 circularity 310:20 circumstance 219:18 339:10 circumstances 148:17 286:22 citation 314:21 322:5 cite 95:13 97:1 99:9 158:12,13 214:4 216:16 216:19 312:9	312:15 314:19 315:1,3,5 321:16,18 334:1 cited 93:10 96:8 96:16,17 98:19 265:6 343:2 citing 98:16 312:14 claim 67:22 166:18 348:3 384:13 387:10 claiming 245:22 372:6 clarice 4:21 114:9 130:16 130:23 clarification 181:15 253:22 398:13 clarify 71:3 78:21 clark 1:14 418:15 classification 241:17 242:7 259:17 classified 284:20 337:17 classify 336:20 336:22 337:9 clean 124:4 157:7 198:10 286:23 304:11 clear 17:19 18:3 36:3 52:3	52:4,20 54:2,23 57:2 58:6 73:13 76:1 90:17,17 92:12 94:12 106:8 155:1 167:21 179:9 189:8 238:17 268:12 274:1 288:18 303:12 323:9 330:7,20 337:7 342:13 342:15 347:18 382:20 396:7 clearly 82:2 91:20 124:1 134:13 135:19 135:21 164:9 169:18 170:16 170:17 181:12 188:1 198:11 199:3 274:5 277:20,21 287:17 308:9 336:24 365:4 379:5 client 31:16 34:2 clients 36:3 clinical 11:15 84:22 85:8 133:10 135:9 136:1 182:3,23 183:5,8 197:21 346:22 402:4 clinically 384:9	close 157:11 394:24 closely 133:3 coauthor 132:5 132:24 407:23 coauthors 132:3 138:7,19 138:24 cohort 4:22 11:22 56:10,19 85:17 91:2,13 91:14 112:3 118:9 119:19 119:19 129:13 134:1,9 136:11 136:16 137:10 137:16 138:12 139:16 140:1,8 140:18,23 141:3,11,17,19 142:8 143:4 154:6 158:7 175:12,18 178:14 195:17 218:11 355:24 385:10 398:10 398:11,16,18 400:8 413:14 413:21 414:23 415:10 cohorts 91:5 113:12 119:20 142:19 144:1 388:14 colleagues 56:9 77:17
--	--	---	---

[collect - complicated]

Page 17

<p>collect 208:24 213:5 308:6,7 collected 86:10 175:12 177:21 357:8 collecting 111:22 141:21 collection 228:1 college 127:9 127:14 column 168:14 249:8 250:11 250:12 276:2 280:17,19 378:11 combination 89:7 339:20 366:11 373:1 384:17 combine 294:14 combined 56:18 142:13 347:11 come 46:4 50:16 52:9,24 55:7 58:5,6 80:17 92:10,17 93:7 135:23 193:1 200:13 298:10 342:14 348:2 366:2 372:11 373:12 396:22 comes 141:14 266:7 365:22</p>	<p>368:21 369:18 405:9 comfortable 247:20 312:4 coming 91:1 115:14 117:17 203:4 216:17 291:17 commenced 112:8 commencing 1:13 comment 57:22 167:5 170:18 401:3,4 commentary 104:6 160:7 201:9 257:3 283:16 commented 72:5 199:13 236:21 commenting 81:23 comments 167:15 commerce 2:8 commission 421:16 committed 183:5 committee 2:16 common 44:15 61:3,4 105:21 106:4 180:7 227:2 299:24</p>	<p>306:10 commonly 312:22 318:4 commonwealth 1:15 communicati... 82:15,20 community 102:1 162:21 312:23 companies 29:16 35:20 346:23 company 18:3 18:4 28:21 29:15,19,22 30:4 31:12 33:9 35:19 46:19 53:20 54:5,12 346:14 405:22 406:2 compare 243:8 318:19 370:16 370:17 compared 223:10 237:8 350:5,15 370:18 378:21 383:13 385:18 394:14 compares 218:10 comparing 243:1 247:7 248:6 394:8</p>	<p>comparison 296:3 compelling 173:17 188:13 403:4 complete 29:19 284:9 297:13 297:16 300:8 304:12 305:21 306:7 307:4,10 307:15,19 308:10 318:5 331:4 332:4,5 333:6 339:15 342:16 343:9 completed 51:1 completely 7:8 29:19,22 36:12 49:18 81:9 95:24 96:14 105:4 119:14 147:23 165:7 216:3 263:4 277:3 297:21 301:23 306:10 341:3 342:13 343:3,8,10 345:24 393:17 395:10 396:13 completion 260:9 261:19 complex 185:4 185:7,8,19 186:5 323:13 complicated 187:11</p>
---	--	---	---

[component - consortium]

Page 18

component 104:2 163:19	417:8	389:8 391:24	considered 57:14 82:17
components 389:17	conclusion 13:22,22 14:12	393:22 396:22	92:5 128:12
comprehensive 55:18 57:3	15:12 52:9,24	396:23	150:16 270:2
221:19	55:7 58:6	confidential 62:22 82:22,24	287:11 315:8
compressed 53:10	152:21 172:10	184:15	390:16 413:17
comprised 268:16	239:19 241:16	confidentiality 60:17 80:8 81:2	414:11 415:6
computation 84:19	242:7 353:11	81:4,11 82:4	considering 15:15 24:21
computational 130:18 340:11	387:16 393:14	83:6 184:11,22	260:8 261:18
computational... 341:16	401:19 403:11	confounders 313:20 322:1	272:16,18
computed 367:1	conclusions 57:23 66:3	confounding 14:13	328:9,23
concept 332:15	156:16 228:10	confused 267:8	consistency 242:9 247:11
363:15	362:22 401:21	confusing 36:13 40:1	248:6 259:19
concern 144:19	404:19	273:16	352:8 385:17
240:3,11	condition 171:1	conjunction 351:13	391:14
289:24 305:19	conditional 326:6 367:11	connect 34:3	consistent 154:4 157:14
349:22 350:3	368:10	connected 35:3	158:5 223:19
350:13 358:6,9	conduct 134:2	connection 195:5,6 291:8	242:17 243:1
concerned 87:4	169:22 413:9	conquers 183:6	243:10 245:1,2
203:17 237:4	conducted 1:12	cons 288:15	245:20 246:6
237:18 387:3	73:24 163:13	consider 35:12	255:13,17,18
concerns 59:2,5	175:11 383:10	62:21 74:11,14	255:24 256:22
63:14 166:23	conference 110:10,11	77:20 79:1	260:13 261:10
200:14	confidence 156:13 157:12	97:22 126:15	261:23 294:10
concluded 13:6	234:23 235:20	127:22 228:22	389:2 391:2,15
13:20 14:17	254:17 282:10	273:18 328:18	398:2,6,9,16,17
152:10,17	339:13 340:2	367:23 368:1	consistently 25:9 244:21
235:8 239:15	364:24 365:14	406:9 409:11	272:22
	365:18 367:10	consideration 128:15	consortium 134:2 137:11
	383:21 384:6		137:16,22
	384:12 386:10		138:6,10,18,23
	388:19,21		

[consortium - correct]

Page 19

139:2,8 140:8	contained	280:15,24	30:23 31:5,10
140:18 194:11	342:4 418:5	282:16 289:19	32:5 33:8,22,23
194:18 413:14	contains 235:1	298:20 330:9	34:1,1,6,7 35:3
413:22 414:23	contaminate	349:5 355:10	36:7 37:5 45:9
415:11	352:4,24	contributed	45:20,24 48:5
consortiums	contaminating	183:19	50:4 54:12,17
194:21	353:2	contrived 75:3	54:21 72:21
constitutes	contamination	76:17	405:14,21
51:12	209:2 352:5	control 56:10	cornstarch
constraints	context 76:21	56:19 85:16	411:7
184:11	85:2 94:15	143:8,9 154:7	correct 8:1,2
construct 130:5	258:8 320:11	158:8 355:19	9:24 10:1 11:3
135:16	322:13 347:2	390:11 398:7	11:4,6,15,23
constructing	357:17 388:24	418:23	12:7 13:10 14:7
151:16	continue 320:2	controls 56:18	14:21 16:2,7,14
constructive	continued 3:1	193:10 223:11	16:22,24 17:7
78:8	continuum	268:24 269:3	21:10,18 22:15
consultant 35:5	50:14	298:7 311:4	22:22,24 23:9
36:18,24 37:10	contradicting	362:20	23:17 24:4,9,10
37:16 121:6,9	213:11	conventional	24:13,23 25:5
consulting	contradiction	104:14	25:20,23 26:2
31:17 32:24	229:1 275:4	convey 340:16	27:1 29:6 30:21
39:12 86:8,22	contradictory	convinced	31:12 32:10
contact 18:12	228:16,17	226:21	33:11 34:5
32:6 34:14	229:15 230:9	convoluted	36:19,24 37:11
60:12 61:11,14	233:14,24	143:15	37:17,21 41:12
62:17 63:9,13	234:7 235:23	copy 9:16,18	41:14 45:16,19
66:18 69:16	269:6,12,16,20	21:9 55:5 342:3	47:4,9 53:3
contacted	270:3,7,9,21	414:1,4	57:7,23 59:1,20
16:11 17:21	271:4,5,7,10,20	corner 213:16	63:24 64:4
18:20 54:21	272:10,15,19	cornerstone	66:22 69:13
59:9 64:1,18	273:6,11,12,22	18:1,2,17,19	72:16 87:13
80:10 90:4	274:2,5,11,15	19:4,7 20:6,13	88:7 102:2,7
406:5	274:20 275:18	20:17 21:2	106:18,21
contain 411:6	276:22 278:3	22:24 28:18,19	111:20 112:3
413:5	279:24 280:3,7	29:5 30:10,19	113:8,14,22

[correct - courtroom]

Page 20

114:12,16	260:14 261:11	269:12	63:8 232:7
115:5,6,9,15	268:17 269:13	correcting	couched 197:2
116:5,19 117:4	270:3,5,21	157:10 162:13	council 3:6
131:24 132:17	272:15,24	177:17 233:13	counsel 7:9
132:21 133:12	275:7,13,19	269:16,19	70:11 121:15
134:4 138:6	276:14,19,24	368:23,24	406:20 408:24
139:6 144:1,6	280:2,3,9,15	369:1	counsel's 257:3
144:10 151:4	284:5 289:21	correction 14:3	406:15
155:8 161:19	290:24 291:24	130:11 229:19	count 41:8
162:22 163:15	292:13 308:18	231:16 233:23	140:3 270:6
163:16 166:16	314:17,23,24	234:14 236:10	counter 335:1
168:19,23	315:7 316:7	266:12 269:6	counterintuitive
169:1 170:11	317:17 318:11	278:24 279:14	320:8 322:18
170:22 174:10	319:20 320:9	279:20 282:16	325:20 334:17
174:13 179:2	327:10 328:1	329:19 347:8	counts 41:4
181:5 184:16	330:11 331:10	367:18 368:22	couple 13:12
188:2 189:23	342:5 347:4,20	376:10 400:15	14:9 83:24
189:24 190:11	347:21,22,24	corrections	151:10 202:24
192:23 193:17	348:22 349:17	25:13 162:15	282:6 377:17
195:21 196:3	350:6 352:4	174:24 283:3	378:2 379:8
197:13 209:23	354:20 355:10	419:4,6 421:7	413:13
210:19 211:3	361:24 362:6	correctly 45:8	course 17:16,21
211:11,14	364:17,20	155:18 219:21	18:7 54:3 69:11
215:4,22	365:12 367:5	326:23 327:2	116:9 142:18
216:18 217:12	369:7 371:1	329:4 334:14	228:13 235:2
217:17 218:18	381:24 383:22	corrects 279:24	312:1 374:12
219:3,16 228:4	385:7 386:17	correlation	382:9 390:22
228:20 230:10	393:4 396:17	257:19 258:2	397:3
230:23 233:2	399:11,23	263:22 269:6	court 1:1
235:21 236:3,6	401:15 402:9	correlations	101:11 122:9
236:8 238:21	404:1 409:2	338:21	158:21 159:11
240:4,12	413:22 415:12	corresponded	419:18
241:20 242:4	416:4,8 418:7	313:23	courtroom
243:5,11 250:6	421:4	corresponding	185:1,16
251:6,23 252:9	corrected 67:14	59:19,23 60:23	404:19 407:18
254:5 255:7,14	234:7,13 238:9	61:5 62:7,18	

[covariate - data]

Page 21

covariate 318:21 320:7 325:19 332:21 338:24	criticism 66:18 74:4,9,11,14,17 76:6 78:6,16,18 78:24 79:8,9,15	curriculum 4:10 29:10 cursor 137:6 cut 12:13,15 cuts 239:7 cv 22:7 29:1,3 30:8,15 31:1 34:3,13 36:17 83:17,21 87:9 94:24 128:12 146:7 cvs 128:13	134:9 138:12 139:16 141:21 141:22 147:19 148:2 149:2,11 153:9 156:7 157:9,9,10 175:17 177:20 185:19 196:22 205:11 208:24 209:2 221:17 228:1,11,16,17 228:24 229:1 229:13,15,16 230:9,10 233:24 234:8 238:4,9 244:8 248:22 252:6 255:3,7 256:5 261:11 262:19 269:6,7,13,16 269:17,20 270:9 273:19 274:11 275:7 275:18,24 278:3 280:1,4,7 280:15,24 281:12 282:16 285:7 286:20 288:13 289:9 289:11,14,15 289:17,19,20 289:23 290:5,8 291:5,17 292:18 294:18 295:7,21 296:8 296:23 297:14
covariates 311:14,19 313:20 318:7,9 318:10 320:4 321:17 322:2 323:19 325:16	criticisms 15:5 41:10 63:11 70:4 73:21 74:2 74:4 75:16 109:18 202:21 309:5 310:4	d	
cover 49:6,6 374:4	criticize 42:1,6 74:19 83:2 201:11	d 4:1 342:2,4 d.c. 2:14 dale 4:18 114:1 116:4 125:9,17 126:6 136:21 137:3 dangerous 328:9 daring 319:16 data 57:4 68:1 82:17 84:20,20 85:2,7,11 86:9 86:11 94:18,18 95:7,8 97:22 100:8,11,11,19 101:14,21 102:1,10,15,19 103:11,12,19 104:1,3 111:22 112:22 117:22 118:10,23,24 119:2,19 124:4	
coverage 416:12	criticized 79:11 107:7,13,22 108:5,8,10,12 110:9 199:21 306:22 314:10 319:15,15		
covers 284:8,10	criticizing 75:19,22,24 76:2,10 111:1,2 111:5,8 303:6		
cowriting 85:15	cross 220:11 383:22		
cox 392:13	crosses 365:4 388:21		
crafting 119:3 119:6	crosstalk 224:17 239:2		
create 334:6	crude 313:22 322:4,7		
created 212:13 212:14 287:4 306:16	ctisi 2:5 cumulative 313:22 322:4,7		
credential 126:16	currently 137:22		
credentialed 130:2 133:1 135:20,22			
credentials 126:4 127:7 128:3 129:23 136:5			
credible 295:7			
crisis 358:10			
critical 248:2,3 291:10,12,15			

[data - department]

Page 22

297:17,18	363:3,8,8	404:15 419:15	defending 9:2
298:5,16,18	367:17 378:7	deal 87:6 96:19	346:15
299:3,24 300:5	379:4,6 380:3	100:7 103:22	defer 326:21
300:23 301:14	381:21,23	130:9 136:2	define 26:15
302:23 303:1,7	382:2 383:19	147:8 230:8,9	86:3 258:7
303:15 304:2	385:10,10	235:3,4 269:22	defined 250:19
304:11,13	389:16 390:2	275:16 286:6	defines 91:17
305:5,14,18	396:7,16 397:1	290:19 293:20	definite 152:1
306:9,16 307:8	402:6 409:12	296:8 304:7	152:19
307:9,11,18,23	dataset 102:15	360:3 384:8	definitely 85:7
307:23 308:1,7	309:20 337:8	dealing 93:22	95:20 163:2
308:8,10,17	353:9	94:3 96:6,21	379:17
311:3,23 313:5	datasets 340:1	100:10 101:13	definition
313:16 316:11	341:15	148:14 149:2	274:2 296:18
318:4 320:4,18	date 16:9,10	295:7	381:17 395:4
321:13 323:18	23:2,3 31:4	deals 327:6	degree 311:1
325:16 326:8	84:1 419:9	dealt 285:2	375:10 408:16
327:9,14 330:9	421:11	316:21 358:16	dementia 87:23
330:19 331:16	dates 27:23	death 290:3	346:21
333:6,14,17	215:20	debate 163:2	demographic
334:11 335:21	davidson 27:9	debating	311:19
335:23 337:6	27:14 28:2,5	164:20	demonstrate
337:11,21,22	72:20	decades 235:10	216:18 226:14
337:22 339:3	davis 373:20	235:19	240:22 401:23
340:17 343:19	day 19:7 20:11	decide 141:18	demonstrated
343:22 348:8,9	20:20,21 21:12	142:4 206:17	385:5
348:10 349:5	26:23 27:1,5	decision 65:12	demonstrates
349:14 352:1,4	347:1 371:7	102:17 153:11	158:15 373:8
352:10,16,24	372:20 407:7	decisions 65:13	demonstration
353:2 354:3,24	421:13	decouple	387:13
355:2,10,11,16	days 16:6 22:23	205:12	denounce 70:21
356:10,13,18	24:9 26:2 50:16	deemed 419:17	denouncement
356:22,23,24	54:13 58:8,20	deeply 324:24	71:1
357:1,3,6,8,11	59:8 151:10	defendant 35:4	department
359:11,13	325:5 345:2	defendants	131:15 172:15
360:5 361:19	403:24 404:7	2:21	173:3

[depends - digging]

Page 23

depends 85:21 99:23 100:11 185:5,20,22 211:12 221:24 255:17 257:6 258:8,10 305:16 338:4 deponent 421:1 deposing 419:14 deposition 1:11 6:1 7:2 13:3 40:12 72:24 190:15,18 384:20 405:5 415:11 417:7 419:3,12,15,17 depth 160:10 181:8 describe 64:11 77:1 229:8,20 229:22 230:7 232:19,22 276:4 308:5 343:10 388:12 402:22 405:23 described 157:17 229:4 230:8 232:24 233:1 313:19 322:1 333:24 376:16 describes 313:15 describing 332:7	description 4:7 38:19 88:10 197:17 230:15 design 86:18 89:4 144:23 169:22 217:23 219:14 227:21 227:22 245:10 286:2,20 288:8 357:14 413:9 designate 40:19 designated 39:6 40:17,22,24 designed 89:3 104:1 129:14 285:22 designing 208:21 283:23 designs 218:15 detail 46:11 196:12 201:19 218:24 321:1 324:21,22 344:18 detailed 250:20 details 198:8 326:19 402:23 403:14,17 406:1 detection 358:11 determine 57:4 89:5 199:2 206:2 215:17 240:22 361:2	determined 151:23 determining 246:5 developed 51:20 251:4 developing 94:17,20 127:18 development 146:13 147:19 diagnosed 176:10,10 179:1,2 237:9 253:10 359:9 diagnosis 412:12 died 308:17 354:15 dies 228:18 275:11 293:22 diette 190:21 190:24 198:15 200:11 diette's 191:24 difference 84:13 287:21 357:22 364:22 372:10 378:21 379:2 differences 13:21 224:4 different 51:24 62:24 63:2 95:24 98:5 115:19 116:21	120:15 123:17 126:3 182:11 193:15 195:19 197:23 217:24 220:13 231:2 243:17 263:5 265:18 266:23 269:2,3,22 277:4,8,13,21 277:21 278:1 283:21 294:19 351:19 356:9 356:15 361:18 372:24 410:13 411:8,8 differential 176:9 178:24 223:7,8 248:18 269:1 298:6,18 308:20 311:2 354:5,13 357:8 359:14 362:16 363:4 378:10 378:13,15,22 379:5 380:2 differentially 237:8 350:4,14 differently 271:5 difficult 84:16 difficulties 286:15 dig 167:20 198:5 401:1 digging 174:20
--	---	---	--

[diluted - douching]

Page 24

diluted 332:22	disagreements 206:19 350:4,6	265:13 387:23
diluting 332:23	402:16	documents 6:7
333:5,8	disappear 371:20 373:2	8:4 140:14
direct 383:4	disappeared 370:15 372:17	doing 12:16
418:23	disappears 371:12 373:15	36:9 48:1 70:15
direction 6:4	disclaimer 169:20 413:6	70:22 80:23
18:22 48:18	disclose 39:14	102:20 123:21
123:18 281:17	343:4	163:24,24
282:18 331:14	disclosed 31:18	204:23 227:10
331:15	32:22 33:2,5	256:13 262:21
directly 96:19	39:9,11,17,24	271:16 273:17
103:6 150:6,8	229:16 342:1	294:1 302:24
399:4	342:22	327:20 330:7
directors	discover 88:17	330:18 341:8
127:17	discuss 16:4	346:7,8,21
disagree 156:23	65:22 81:6	357:23 404:22
158:14 159:23	148:16 149:3	419:8
159:24 163:21	203:3 315:11	double 59:21
164:16 185:14	317:4	132:9 311:3
189:4,6 213:12	discussed 14:20	354:10 413:23
220:13 229:3,5	94:14 104:17	doubling
272:20 282:5	148:12 238:22	362:18 372:18
326:1,4 377:12	288:14 317:8	372:19
377:14 399:19	368:19	doubt 12:10
400:4,9,12	discussing 13:2	19:12 23:3
401:10,18,20	146:6 253:5	122:2 126:4
402:3,8,12,14	discussion 8:19	129:23 132:14
403:2,7,11	48:19 156:14	133:14 138:21
406:17 407:2	412:7	139:11 192:7
disagreed 174:8	disease 125:11	292:6 308:22
174:9	126:7 129:7	doubting 127:6
disagreeing	205:19 206:4	128:2 132:8
174:10,14		douche 359:12
disagreement		douching 115:3
220:4 353:19		175:21 195:15
		227:1 239:24

[douching - enhanced]

Page 25

241:8 242:17 243:2 247:2,4 263:20,21 272:7 359:2 377:23 379:4 downloaded 54:9 dr 7:20 59:18 61:8,20 82:14 83:16 115:8,8,9 120:6 123:4 136:3,11 138:4 138:5,5 139:4,8 146:3 151:1,1 190:20,24 191:24 192:23 195:6 198:15 200:11,11 239:11 374:24 386:13 388:3 407:7,9,10 408:10 414:11 416:1,17 draft 51:8 drafted 58:23 77:18,19 120:8 drafting 59:10 120:8 122:2 404:14 draw 74:16 driving 256:2 dropped 40:3 drug 206:18 328:12 dry 374:11	drye 37:9 39:23 40:2 41:3 due 7:5 308:21 384:10 dug 201:18 duly 7:13 duration 154:9 158:10 383:12 388:15 durations 13:9 dying 308:22 310:23 e e 4:1,6 94:10 418:1 420:2 earlier 175:16 178:18 188:21 244:12 247:19 290:22 372:11 384:20 391:1 402:8 409:1 earliest 219:11 313:24 early 219:22 easier 9:12 10:9 247:18,22 265:24 easiest 278:16 easily 371:20 eastman 46:1 48:5 economic 46:12 editing 51:13 51:16	editor 5:11 69:19,23 70:8 70:23 71:9 110:11 117:10 162:6,6 167:5 190:16 386:15 editorial 110:12 190:9,16 192:3 192:12,13 195:5,10,24 197:13,22 199:14 373:16 373:20 376:2 401:12 editorials 402:21 editors 116:17 165:13 180:17 education 409:24 410:10 effect 205:13 243:12,18 255:22 259:23 262:20 375:7 effective 252:14 254:11 effectively 263:1 307:9 effects 358:12 359:16 383:8 383:11 394:5 efficient 318:5 egregious 82:8 eight 24:8 26:2 50:16 166:15 168:3 345:2	either 28:5 40:19 85:16 93:18 119:24 162:18 181:6 186:2 199:20 287:8 292:16 295:15 326:3 327:24 331:2 elected 131:6,9 element 292:8 eligible 266:6 266:11 279:14 279:20 email 60:24 61:6 71:10 184:3 232:8,8 232:20 emails 62:15 emphasized 207:18 employ 273:19 312:22 employee 35:14 35:15,18 endeavor 69:12 endeavors 17:17 ends 194:16 engage 79:18 engaged 124:20 engagement 160:20 english 44:16 enhanced 146:10
--	--	--	---

[enroll - everybody]

Page 26

enroll 225:1	entirely 16:20	equations	282:20 300:21
enrolled 111:19	259:24 276:13	96:12	322:7 359:16
219:20	389:14	equivalent	364:18 365:13
enrollee 210:18	entitled 66:1	307:13	366:2 367:6
211:16	115:2	err 81:5 83:5	380:20 383:24
enrollees 211:1	environmental	errata 419:6,8	386:7 388:16
211:6,7	4:12 125:12	419:11,14	389:6 390:9
enrolling	129:14,17	421:9	396:9
219:12	131:23 132:17	error 279:11	estimates 156:9
enrollment	168:7 173:23	311:18 384:11	260:11 261:21
142:16 144:6	epidemiologic	errors 176:7	262:20 313:23
209:21 210:9	85:15 100:8	178:23 180:16	322:4 339:2
211:8,17,22	101:24 103:22	180:20,21	375:7 397:7,9
212:13 213:4,7	131:10	181:5 182:2	estimating
213:9 217:24	epidemiologi...	306:14	209:11 301:14
218:10 219:14	84:12	especially	330:16 383:11
219:20 220:9	epidemiologist	58:16 175:21	estimation
229:14 242:20	84:9,15,21,24	176:5 178:20	206:8
243:4 263:3	85:14,19 86:3	178:20 186:17	estimator 319:4
269:24 270:15	87:3 129:7	esq 2:3,8,13,18	et 88:6 195:11
273:5,7 276:12	epidemiologi...	3:3	375:5
278:11 279:8	46:9 355:16	essential 320:9	evaluate 263:16
279:13,13,19	356:19,22	322:19 325:21	evaluated
280:5,8,16	epidemiology	326:20 334:18	359:19
281:9 290:2	125:10,11	essentially	evaluating
351:14 354:8	126:7,8 127:10	223:21	55:23
354:12 411:23	127:14 129:12	establish	evaluation
412:14,20	135:9 137:12	410:16	55:18
ensure 7:7	205:20 206:2	established	evening 407:7
entails 170:14	206:15,17,22	134:1 137:17	event 319:3
entered 349:3	218:8	150:20 416:3	382:5
entering 253:1	epithelial	estimate 27:18	events 314:1,4
enters 293:14	137:24	73:2 156:12	everybody
entire 245:18	equation	204:13,24	166:19 189:18
287:11,13	233:11	234:21 235:22	189:19,20
		236:9 261:6,7	232:2 280:7,22

[everybody - expected]

Page 27

294:10,12 397:3 everyday 408:5 evidence 15:22 120:6,16,24 121:10,17,22 121:23 122:6 122:14,18 124:16 136:6 154:8 158:8 173:17 188:13 190:24 214:3 224:2 239:16 250:4 254:21 255:1,12 256:20 261:9 352:2,13,15 403:5 411:12 418:5 exact 18:24 72:12 123:21 207:20 243:10 278:16 292:3 326:19 exactly 20:16 26:15 28:20 35:22 53:8 74:15,18 81:3 177:4 220:2 222:1 239:12 254:18,18 261:14 269:15 277:19 287:16 312:10 337:4,5 355:4 362:14 395:20 412:2	exaggerates 310:14 314:16 examine 174:21 180:4 195:19 197:10 examined 7:13 178:5 examining 359:17 382:14 example 21:16 48:10 64:18 65:10 67:22 70:7 80:19 85:16 88:5,15 96:11 99:13 105:9 116:16 127:3 221:15 225:10 228:18 231:14 263:11 264:3 274:6 275:10,14 295:5,6 309:6 309:16 328:11 333:11 340:15 351:2 357:7 362:9 368:7 370:9 379:14 394:9 examples 301:9 311:19 376:17 except 41:3 43:15 248:19 283:5 421:6 exchange 69:4 exclude 300:6 300:12,14	exclusion 300:7 excuse 128:22 156:19 executive 3:4 exercise 79:19 exhibit 4:9,10 4:11,12,13,14 4:15,16,17,18 4:19,21,22,23 5:1,2,3,4,5,6,7 5:8,9,10 9:19 10:5,11,13,15 10:16,20 11:13 13:23 16:14 19:18,24 23:7 24:12 26:5 29:4 29:11 30:15 45:7 50:19 60:21 83:18 111:13 112:9 112:17 113:13 113:17 114:18 114:22 115:19 115:21 116:1 116:10,18,21 116:22,23 117:2,11 125:7 125:18 128:19 128:21,22 129:2 130:15 130:24 132:6 133:8,18 136:10,17 140:20 149:16 149:24 153:24 154:1 155:23	158:3,4 165:18 165:24 166:24 173:13 174:1 182:14,18 186:8 190:6 191:16 193:6 193:21 210:24 212:24 213:15 214:13 215:11 216:4,21 230:5 239:24 241:12 247:5 260:3 278:18 298:23 299:9,23 313:10 315:19 315:24 373:19 374:24 382:17 387:5,18,19,22 391:21 413:14 414:13,17 exist 358:12 366:8 401:5,6 existed 14:18 existing 102:9 exists 124:21 125:5 240:9 253:16 312:1 350:20 411:1 expanding 359:7 expect 118:5,22 377:5 expectation 147:22 expected 64:11 363:19
---	--	--	---

[expensive - factors]

Page 28

expensive 340:10 341:16	284:15 311:15 311:20 312:7	exposures 129:18 195:21 196:13 298:6	f f 418:1
experience 83:22 84:5,11 104:16	377:10 401:13 explained 70:9 184:7 232:14 390:14	express 200:14 407:15 expressed 71:23 198:16 198:17,21 201:20 400:11 403:21	face 174:19 180:9 181:9 187:14 364:4
experiment 64:12	explaining 86:1	extension 36:8 228:6	facilitate 137:17
experimental 86:18 286:1	explanation 237:10	extensive 92:7 175:10	facilitating 141:6
expert 4:9 10:19 31:11,17 32:10,12 33:24 35:18 36:23 37:9,16 38:1,16 38:21 39:6,13 39:17,24 40:5,9 40:24 44:23 81:22 84:11 98:2 121:9 198:2 246:24 405:16 406:12	explanatory 308:3 explicit 273:4 306:7 explicitly 174:13 210:3 223:3 227:17 270:6 402:17 402:19 exposed 207:4 207:16 208:9 209:7 254:4 280:22 287:21 287:22,22	extent 22:3 31:16,23 39:8 39:11 41:14 50:9 82:14 83:24 92:23 97:12 100:12 103:24 119:9 145:10 381:4,7	facing 357:4 fact 22:19 24:7 48:2 62:19 66:21 70:5 134:11 140:24 163:15 189:10 207:3,15 210:5 237:5 238:24 239:14,14 271:21 273:21 293:23 309:1 315:2 320:8 325:20 334:18 337:9,20,23 341:1 349:22 352:5 386:9 411:18
expertise 130:8 134:19 151:4	exposure 103:2 106:20 115:5 154:8 158:9 195:19 196:15 196:17 206:19 209:17 212:13 213:20,21 216:12,13 225:3,4 250:19 272:4,5 288:3 298:6 350:5,14 359:13 360:12 360:14 375:15	extra 103:12 169:16 222:11 223:15 372:21 extramural 133:24 extrapolating 291:16 extreme 282:7 282:14 extremes 281:22 282:10	factor 4:12 89:6 173:23 276:16 386:10 factors 88:16 88:17 89:7 91:13 129:15 134:3,10 135:17 137:18 150:19 305:17

[facts - first]

Page 29

facts 82:17 faculty 131:15 fail 419:16 failure 322:17 322:18 fair 17:14,18 73:12 87:1 117:14 303:13 346:1 fairness 308:16 faith 93:11 fallopian 388:9 false 187:22 familiar 49:18 92:12 104:8 126:1 140:17 familiarize 92:15 93:5 fancy 100:18 far 30:2 178:3 179:12,12,13 196:20 198:12 204:20 222:10 231:24 306:8 307:4 341:23 385:23 388:5 fashion 55:8 121:6 238:10 fast 110:4 193:13 259:10 fatal 310:11 311:9 fault 285:9 favor 328:1 fda 328:13	feature 171:19 171:23 172:4 176:24 277:2 277:10,14 featured 172:21,22 173:8 features 276:7 feedback 311:18 314:13 325:8 334:6 368:20 feel 265:19 374:11 feeling 79:10 fell 278:8 fellow 131:6 feminine 242:8 247:10 248:5 259:18 field 105:6 150:21 158:24 159:14 194:8 207:22 fields 34:16 46:12 fifty 73:5 figure 47:2,6 97:15 205:17 265:7 349:7 filed 24:8 28:3 28:9 50:15 fill 26:21 228:19 275:12 308:8 327:9	filled 303:17 filling 304:1 final 167:7 332:7 finalized 28:4 finally 50:16 find 24:18 25:1 25:8 33:20 35:19,24 36:11 79:13 124:21 125:4 246:11 247:22 286:10 318:20 332:18 335:20 342:3 379:12 finding 333:2 findings 262:9 404:18 416:10 finds 29:16 33:10 241:9 380:18 fine 9:14 39:10 47:7 54:20 65:9 145:18 148:7 170:6 202:11 310:22 323:17 finish 49:10 65:8 123:3,4,8 123:11,14 157:1 160:3,4 191:21 201:6 222:24 245:9 257:13,13 294:6 297:10 303:23 379:11	firm 2:2,7 37:5 37:6,8 38:23 41:24 firmly 68:6 firms 36:5,18 38:22 39:4 41:1 405:16 first 16:10 19:7 20:11 21:1 26:6 26:23 27:1 28:1 34:22 35:4 40:2 41:23 42:12 43:2,7 51:19 52:8 59:22 80:21 90:1 103:21 113:23 138:14,16 150:24 161:16 175:24 187:15 202:23 203:2 214:12 217:1 220:17 222:5 223:3 227:3,11 227:12 228:15 241:14,24 244:3 245:4,10 245:23 246:7,8 246:12 250:10 251:1 255:13 256:23 257:19 260:19 263:17 264:16 269:23 270:13 271:17 272:9,13 274:7 275:1,11 276:1 276:7,17,21
---	--	--	---

[first - form]

Page 30

277:14 285:20	400:20 401:5	280:18 281:10	42:15 43:5 44:7
285:22 286:17	flexible 299:2	281:12,24	45:1 47:10,19
286:22 291:7	flip 189:13	284:14 285:1	48:15 49:7
302:2 328:24	372:15 417:4	288:14,17,20	50:20 51:8
329:7 330:5	flipped 233:8	290:12,16	52:11 53:4
353:12 359:23	flipping 177:17	297:16 304:13	54:15 56:13
359:24 372:18	229:19 238:4	304:17 305:4	57:9,24 58:11
372:22 415:9	349:19 365:17	307:3 332:9	59:3,14 61:16
fit 294:21	376:17	333:9,12	62:1 63:16 64:5
five 16:6 27:19	florida 2:4	337:12 354:8	64:23 65:17
41:8 140:9	focus 87:12,15	354:11,15	66:11,23 67:8
145:16 202:3,9	88:3,6 89:5	360:5 362:19	68:15 70:10
258:14 266:12	144:24 196:7	412:15,20	72:3,10 74:12
266:13 369:13	245:21 250:10	followed 176:1	75:6,20 76:9
369:17 391:16	250:11 347:14	231:20	77:3 81:24 88:8
399:3	focused 49:22	following 216:3	90:6 91:8,15
fix 305:7	84:18,21 96:5	323:23	97:9,19 100:20
355:14	124:5 135:9	follows 7:14	101:16 102:3
flaw 180:7	230:19	font 278:20	107:10 108:17
310:11	focuses 175:5	footnote 12:21	109:21 110:15
flawed 22:21	176:20 196:1	316:17 325:21	111:6 112:10
24:22 25:15	follow 106:13	334:3 342:2,4,6	112:24 117:19
42:14 43:4,14	112:23 113:2	footnotes 96:9	118:11 119:21
43:22 44:5,16	119:4,6 141:13	154:13,17	120:21 121:14
44:18 50:8	143:16 144:24	forced 222:7	122:15 124:22
51:21 52:1,5,10	161:8 177:3	foregoing 418:6	126:17 127:23
53:1 55:8,11	213:10 214:18	418:21 421:3	138:13 139:18
66:3 75:1 76:16	217:2,10	forever 95:1	140:11 144:17
110:20 123:19	225:14 241:18	forget 72:12	145:6 151:5
134:13 175:1	242:19 243:4	296:7	155:9 156:2
185:11 227:22	249:19 250:20	forgive 273:14	157:20 159:1
305:4	260:9 261:19	273:15	159:16 162:23
flaws 80:16	263:1,24 270:1	form 15:18	164:13 170:19
133:4 167:7	270:24 273:5,8	16:23 18:10,15	172:1,8 174:11
181:11,12,18	274:6 277:22	21:4 23:19 30:6	177:2 179:18
181:22 186:22	279:20 280:5	35:9 36:10 42:3	180:24 191:13

[form - genital]

Page 31

194:13 196:4 198:19 199:23 204:4 205:5 207:5 210:10 221:10 225:6 226:10 231:5 232:10 233:4 236:18 237:13 240:13 243:14 246:19 251:24 255:15 256:7 257:22 267:16 268:18 273:1 280:10 291:1 292:1 293:3 296:15 303:2 312:24 319:21 320:21 329:14 343:21 345:4 345:14 346:2 349:23 352:17 354:22 357:19 362:1 370:20 394:2 395:16 396:18 398:4 399:12 400:22 403:8 404:2,10 405:2,17 421:7 formally 70:4 formed 50:7,10 forming 50:11 forth 10:10 248:1 376:19 forum 200:15 forward 12:24 124:3 200:13	301:2 306:12 found 29:24 31:11 33:22,23 34:18,19,21,22 43:10,22 48:5 53:20 177:20 186:11 212:12 233:13 234:6 244:19 247:8 248:3 255:12 263:21 286:7 345:7 388:5 395:12 four 41:2 64:3 231:2 233:20 292:23 307:19 347:3 367:14 386:10 399:3 fourth 242:15 242:21 250:20 375:1 frame 203:1 217:9 219:15 frames 222:17 224:24 frankly 363:20 free 175:19 265:19 345:23 frequency 154:9 158:10 392:11 393:4,7 394:5,11 395:5 frequent 14:4 369:5 394:8,14 394:23 396:16	frequently 13:9 186:17 235:9 front 8:6,11 9:16 23:7 106:9 132:7 183:14 froze 124:13 152:13 170:2,4 fully 13:11 84:3 84:17 180:16 248:22 250:22 251:7,15,20,20 251:21 252:2,5 253:9,17 261:11 276:2 311:20 377:10 407:11 416:3 418:5 fundamentally 288:10 funded 413:6 further 126:24 163:23 188:4 261:8 282:22 303:11 319:9 furthermore 252:19 fussing 178:13 386:6 g gain 223:15 game 229:7,9 gap 212:12 gaps 304:1 garbage 288:24 289:2,6,7,8	gathering 356:13 general 15:14 77:13 79:13 89:1 96:11 100:22 148:1 203:8 241:9 264:13 291:12 332:3 361:15 377:5 380:9 401:21 generalization 360:17,22 generally 84:18 87:2 93:6 98:11 101:7 184:23 255:9 301:20 350:11,12 356:23 generate 16:12 16:22 17:1 24:7 32:13,19 47:1 48:4 58:15 generated 14:1 39:5 47:8,13 56:11 generating 11:10 45:10 51:22 genetic 129:15 genetics 133:10 genital 13:6 14:1 24:20 25:10,14 115:3 156:10 173:17 175:20 186:10
--	--	--	--

[genital - going]

Page 32

188:14 193:7	give 9:8 40:22	136:24 137:15	332:13 335:14
195:15 203:11	85:23,23 95:14	140:20 146:21	336:3,11
204:13,16,24	106:6 127:2	151:8,13,14	338:15 356:14
205:13 207:4	144:18 145:8	155:16 157:21	359:3,3 361:16
207:16 208:9	162:10 165:20	157:22 158:2,3	373:18 377:16
208:15 209:7	266:3 279:6	165:12 167:23	379:18 380:7
209:12,14,17	283:11 293:7	169:9 179:8	380:16 381:10
210:2,7 211:9	293:13 320:12	180:3,10	387:2,20,21
212:16 227:1	345:16 366:18	183:13,15	388:1 392:7,18
233:17 234:11	374:2,6,7,10	193:6 195:4	393:13 397:1
242:16,24	389:23	196:12,20	402:22 403:17
249:9 250:2	given 20:20	198:8 204:19	goal 16:12,16
260:12 261:21	44:3,9 128:10	209:19 210:16	23:16,20 88:16
262:11 264:7	211:21 226:16	210:20 212:23	204:12,15,23
265:1 267:3	237:6 377:1	212:23 213:2,3	205:3,8 207:8
276:9,12 281:6	389:12 404:24	213:14 214:6,9	goals 206:1,15
281:7,8 291:22	421:5	216:4,21,24	206:17
309:23 359:1	gives 60:24	218:17 226:23	goes 141:23
359:12,18	157:11 184:2	230:4 241:8,12	162:13,16
375:6,19 377:8	222:5 223:6	242:13,14	169:12 178:19
377:10,21	giving 321:5	244:1 247:1	227:3 281:16
378:11 383:9	glasses 266:5	249:20 250:9	298:21 300:15
388:7 396:10	glue 294:20	250:14,17	301:11 318:18
401:14 403:5	go 8:12,15	260:5 264:14	325:2 344:23
410:3 411:13	10:10 13:23	264:17 269:8	379:15,22
412:13,15	24:15 26:4 30:1	278:22 279:23	384:2 389:16
genuinely	31:7 36:16	282:22,23	406:4
385:1	44:13 45:6 48:2	286:2 297:10	going 10:11
georgia 2:19	65:20 70:21	300:19 301:24	15:10,10 19:3
gerel 2:12	74:6 75:2 77:6	303:11 309:13	20:23 27:24
getting 32:16	81:8 111:12	313:9 315:19	36:5 61:3 66:6
56:2 122:20	123:17 125:7	319:2,8 320:24	68:5 74:24
239:5 249:11	126:5 127:1	321:22,23	76:12 77:12,15
267:8 336:14	128:23 130:15	322:14 324:14	77:24 80:15
376:13 393:12	131:4 133:3,8	327:3 330:24	82:13,19 83:4
	133:22 135:1	331:1 332:6,11	95:4 97:14 99:4

[going - hand]

Page 33

100:14 101:8 101:10 106:20 107:5 111:13 118:8 124:9,10 124:11 127:2 136:10 138:15 141:9,22 142:4 142:22 145:13 145:13,15 148:8,10,19 151:7 152:4 155:3 159:9 160:12 161:6 171:9 179:10 179:12,20 182:9 186:7 187:3,8 190:1 193:13 199:8 202:1 215:2,15 222:13 223:13 227:15 241:10 250:11 254:23 257:5 258:11 259:9,9,10 264:18 273:17 273:18,20,22 282:13 289:2 297:20,22 310:19 311:5 315:17 319:10 319:18 320:14 322:23 323:2 326:5 328:13 328:15,19 330:22,24 331:9,18 332:1	336:1,10 337:8 338:15 339:4 341:10 344:15 345:22,22 361:14 367:2,3 373:21 374:24 375:9 378:7 379:8,12 390:24 391:14 399:2 405:15 406:18,22 407:3 414:7 416:23 gonzalez 5:3 112:6,16 113:8 203:5 210:17 210:23 285:5 287:3,8,17 380:17,17 385:6 good 12:18 81:16 88:10 93:11 99:8 102:21 128:1 141:2 184:5 196:15,16 202:6 218:14 220:15,16 227:21 242:9 247:10 248:5 257:18 258:2,4 258:8 259:19 260:19 283:6 283:22 289:15 324:1 339:9 340:13 402:5	407:6,7 416:20 goodman 36:22 41:4 google 47:1,16 47:21 gotcha 254:20 gotten 128:7,8 grant 168:19,20 168:22 169:3 171:2 grants 169:2 170:1 graph 47:6,8,8 47:13,17 great 128:5 174:23,24,24 199:11 202:7 218:24 323:5 324:5 greater 235:10 235:13,18 383:13 386:17 greatly 106:3 133:1 greg 46:1 group 125:11 126:7 129:7 161:7 182:1,8 183:21 196:16 196:18 223:22 273:11 411:20 groups 127:4 254:13 guarantee 251:9,12,17 255:5 399:6	guarantees 251:19 guard 102:20 guess 99:17,18 99:21 100:18 102:1 247:24 291:22 292:18 292:20 293:1 332:14 398:19 417:1 guessing 226:8 226:9 253:11 253:13,20 292:7,9,13 293:22 guesswork 307:23 337:21 339:1 guide 299:1 302:15 gynecologic 139:17 377:2 gynecological 135:10 140:3
			h
			h 4:6 hagelund 183:23 half 112:7 146:3 375:15 hamilton 36:23 41:4 hand 170:1 249:8 250:1 261:1 313:13

[hand - hormonal]

Page 34

<p>359:4 383:2 handful 371:13 handles 301:14 handling 299:3 happened 357:18 390:14 happens 356:6 happily 414:9 happy 77:8 155:20 239:22 320:13 322:11 373:23 hard 9:16 164:10 340:9 363:24 harm 102:21 harris 3:3 4:14 114:6 191:15 193:14,17 197:22 373:19 401:11 haven 305:21 306:5 haynes 37:20 39:18 hazard 156:9 157:11 233:15 234:8,22 236:22 237:19 261:6 310:6 313:22,23 314:16 322:4,7 327:23 328:22 329:9 330:23 331:10 347:4 347:15 348:12</p>	<p>348:19 352:11 364:16,19 367:7 372:21 373:12,13 380:18,21 381:9 383:21 384:1,19 385:20 386:7 389:5 391:5,23 393:23 394:10 394:13 395:19 397:20 hazards 4:24 149:23 392:14 head 55:11 127:4 132:14 279:5 headed 131:17 header 265:18 headhunter 405:13 headhunters 405:23 heads 126:6 131:21 health 104:1 125:13 131:23 132:17 142:10 143:24,24 168:7,8 169:21 203:22 205:4 356:3 413:7,8 hear 172:2 191:10 198:17 234:4 239:8</p>	<p>heard 7:8 42:5 198:22 344:14 415:10 held 8:19 help 17:22 86:12 103:3 246:4 393:11 393:13 helped 89:4 helpful 95:3 helping 86:17 86:18 helps 129:12 173:7 306:17 306:21 342:8 henrich 3:3 hesitate 13:13 hide 95:11 hiding 231:4,8 hierarchy 126:2,22 high 253:8 higher 14:4 56:3 95:8 328:20 361:10 378:20 394:10 394:13 397:24 highlight 261:13 276:18 highlighted 172:5 176:16 176:19 206:7 261:16 323:21 highlighting 173:14,15 383:24</p>	<p>highlights 176:22 highly 135:11 140:17 297:17 298:6 hill 3:4 hired 9:1 107:20 109:19 110:8 236:13 hiring 128:11 histologic 134:4 history 5:8 134:15 165:17 165:23 359:1 413:2 hobby 346:12 hold 123:2,2 191:4 222:23 222:23 249:20 257:12 294:5,5 303:22,22 397:13,13 408:14 holds 169:21 301:23 324:24 hole 294:22 305:11 holly 114:6 honest 141:4 173:9 225:7 honestly 206:10 207:12 220:18 256:3 hopefully 203:1 hormonal 186:18</p>
---	--	--	---

[hormone - imputation]

Page 35

hormone 9:6 129:18 359:7	iarc 4:23 149:21 150:3,4 150:5,10,16 152:21 157:17 415:23 416:1	ignored 167:5 181:7	important 91:6 91:14,18,19 103:17 125:23 126:20 150:17 172:7 203:20 205:3 206:24 207:13,19 208:7,11,14,18 228:21 288:3 300:6,13 332:17,17 333:1,5 382:21
hour 73:9 145:15 146:3	idea 52:17 95:6 102:14 138:11 205:16 220:8	ignores 365:23	
hours 50:1,2,6 53:19 54:11 58:17 73:1,4,5 73:10 404:13 405:19	ideal 311:13 336:7	ignoring 306:14 363:2	
hr 396:9	ideally 231:22	ii 146:13	
huh 30:17 214:19 266:8 317:2 378:6 409:3	identification 4:23 10:6,20 20:1 29:12 112:18 113:18 114:23 116:1 117:11 125:19 129:3 131:1 133:19 136:18 149:22,24 166:1 174:1 182:19 191:17 193:22 215:12 299:9 316:1 414:18	illusory 306:6	
humans 4:24 149:23		illustrate 80:15 361:23	
hurts 78:7,9 79:9		image 95:9	
hygiene 242:8 248:5 259:18		imaginary 229:7	
hypothesis 262:10 328:11		imaging 87:13 87:16,17,21,22 88:1,1,6 146:9	importantly 318:10,15
hypothesized 383:6		impact 176:7 178:22 195:12 394:7	impossibility 80:21
hypothetical 122:21 123:1 283:11 293:8 293:13		imperative 419:13	impossible 387:11
hypothetically 143:19		imperfect 162:2	impression 228:5,9 287:4
hysterectomy 385:11		imperfections 162:22	impressive 126:16 127:22
i		implementing 94:21	improper 80:17 303:8
i.e. 195:15 305:22 412:24		implicate 410:17	improved 163:4
	identified 32:10 40:9 92:14 93:4 138:1 182:2 345:1,2,6	implication 226:2	imputation 13:4 48:11,13 64:19,20 65:14 93:18,21 94:2,2 95:15,21 96:5 96:12,20,23 97:6 99:16,20 100:3,4,6,9,17 100:22 101:12 101:19 102:18
	identify 93:24 95:2 129:14 166:24 275:2	implicit 335:21	
	ignore 351:11 351:21 362:21 362:22	implies 177:14	
		imply 225:22 352:21	
		import 203:8	

[imputation - incorporating]

Page 36

102:21 103:3	318:7 319:5,17	157:9 291:5	290:3 314:9,12
103:10,16	321:18 322:2	308:13 343:15	314:14 316:5
104:10,23	326:10,17	inaccurate	319:3 321:16
105:2,10,23	327:3,5,8	415:9,13	331:21 333:24
106:1,4,10	328:21 329:21	inappropriate	334:16 342:23
107:8,13,23	330:21 331:8	59:16 60:2,5,9	343:1
130:11 132:21	332:19 334:1,5	80:12 309:19	inclusion
146:6,18 147:1	334:16 335:4	335:18 365:16	309:24
147:8 148:13	335:11,16,17	inappropriately	incomplete
148:14 149:1	335:24 336:2	107:14 108:11	102:15 297:17
177:18 189:11	337:21 338:18	incidence 9:5	298:17 318:9
189:14 229:16	339:19 341:5,7	137:24 156:8	320:4 321:13
234:1 235:24	341:11,14,17	262:12 359:6	323:18 325:16
236:6,10	342:22 343:5	incident 250:21	342:20
238:12 266:7	343:10,12	include 129:17	inconsistent
269:8,13,20	344:7 349:6	187:17 195:18	155:7,24
289:10,21	354:20 355:7	301:1 311:10	156:17 238:5
290:21 291:3	376:10 400:15	312:8 318:17	272:24 380:6
291:11 293:20	408:19 409:6	319:16,19	385:4 386:5,8,9
295:6 297:3,19	imputations	322:17,19,24	387:17
299:2 300:20	25:13 320:17	332:18 333:2	incorporate
300:24 301:1,3	336:18 339:10	334:5	188:20 317:13
301:10,13	339:11,20	included 309:9	317:21 327:14
302:2,5 303:8	340:5,10,16	313:19 321:24	327:24 336:1,6
304:16,19,20	341:9	334:22 344:8	incorporated
305:16 306:11	impute 103:17	344:13	222:10 292:17
306:13,17,21	105:19 106:20	includes 137:23	326:16
307:22 308:9	264:6,24	266:16 269:12	incorporates
309:10,19	290:17 303:15	318:15 381:17	175:14 178:16
310:11,16,17	304:12 307:12	413:18	304:16 326:17
311:5,6,8,9,10	308:14 309:23	including 13:3	incorporating
311:13 312:4	318:4 333:17	38:22 48:12	144:20 235:23
313:14,21	imputed 337:6	53:19 70:7	316:11,22
314:15 316:6	340:1	142:10 154:7	326:8 329:21
316:15,23	imputing 95:7	158:8 176:9	330:15 355:9
317:23 318:2,3	95:8 102:24	178:24 179:14	355:11 359:8

[incorporating - intentionally]

Page 37

360:4 402:6 incorporation 187:20 incorrect 42:11 273:3 403:16 increase 233:16 339:12 375:5 375:16 379:19 379:21 392:11 393:4,7 394:6 394:11 396:15 397:22 increased 173:18 188:15 234:10 235:12 235:14 237:11 252:8 314:13 360:13 369:6 385:9 403:6 411:22 412:19 416:12 incredible 369:10 incredibly 364:8 independence 122:2 independent 9:9 16:17,21 17:3 20:24 23:24 145:8 190:23 191:1 345:9,16,21,24 346:6 405:7 406:9	independently 18:4 22:17 58:2 63:20 71:14 92:22 97:7 110:18 181:10 184:9 256:6 index 6:1 indicate 376:22 412:22,23,24 indicated 324:20 353:7 indicates 67:11 67:19 285:7 indication 252:22 indicative 198:13 indicator 319:4 indicia 251:22 indirectly 150:7 individual 56:21 64:20 103:15 363:16 individually 135:19 individuals 76:2 86:19 370:4 402:15 induced 319:12 inducing 410:17 inference 144:19 328:10 409:17,21	inferences 313:5 inflated 368:13 372:18,21 inflating 384:18 influenced 60:19 influencing 105:24 information 31:20 32:1,16 33:2 39:14 63:11 64:14 103:5,8 106:12 121:3 153:9 154:24 173:5 175:11 213:5 226:17 263:2 276:8 292:17 294:15,17 300:7 308:2 338:5,23 340:17,23 344:9 356:14 384:22 infrequent 369:9 372:1 inherent 306:15 initial 19:5 27:14 28:8 209:21,24 216:7,8 241:19 242:2 292:20 348:9	initially 175:18 213:17 initiated 144:12 144:13 initiative 142:10 144:1 356:4 inner 167:6 inquired 263:2 insignificant 373:14 institute 125:12 131:23 132:16 133:11 168:6 396:8 413:19 institutes 168:8 169:21 413:7,8 institution 34:11 instruct 82:13 82:19 406:18 406:23 instructions 419:1 intact 383:19 388:9 integrating 359:11 intend 404:18 intended 79:18 intent 124:20 intention 404:21 intentionally 12:14,16 167:11
--	--	---	--

[interest - johnson]

Page 38

interest 65:3 84:23 328:3 346:22 interested 61:10,13 86:23 208:23 345:23 interests 129:16 interim 146:4 internal 126:2 126:21 171:16 international 137:11 149:17 150:17 internationally 135:11 interpret 323:16 interpretation 85:1,6,11 169:22 204:22 384:4 413:10 interrupt 65:8 74:6 81:15 170:3,5 252:3 interval 156:13 157:12 222:7 224:15 234:23 235:20 254:17 263:7 339:13 364:24 365:14 365:18 367:10 383:22 384:6 384:12 386:10 388:19,21 389:9 391:24	396:23,23 intervals 222:2 222:4,12,20 223:15 227:18 245:12 277:22 277:24 282:11 340:2 intervening 412:12 intimate 9:4 175:13,19,20 176:8 178:15 178:23 195:14 213:16 216:8 224:23 359:6 intramural 126:9 168:5,20 169:2,3 intramurally 171:3 introduce 251:23 357:8 introduced 218:3 243:24 354:1 introduces 355:5 introducing 218:3 investigator 125:10 130:17 133:10 135:2,5 investigators 210:6 212:5,11 262:23	invited 192:11 401:12 invoice 45:7 72:11 involved 30:24 37:8 38:23 85:1 85:6 86:23 89:10 119:6,7 120:20 121:18 130:10 139:16 140:1,6 147:18 148:24 150:4,5 166:20 194:8 344:17 390:15 405:14 407:22 involvement 88:11 involves 233:23 233:24 409:8 irrelevant 258:1 311:1 312:21 issue 89:14 190:5 205:4 207:1 374:6 399:11 issued 141:13 issues 43:11 58:7 84:6 87:6 88:4 92:1 95:18 96:3,19 130:10 160:11 185:4,8 201:19 352:6	j j&j 16:9 17:20 18:11 19:1 20:13 23:15 33:20 143:4 158:20 159:10 199:19 399:10 j&j's 16:3 19:6 21:2,13 22:20 159:8 201:10 jama 5:5 299:1 299:8 302:15 janet 131:8 january 166:12 jco 190:4 197:20 jeff 115:21 158:3 166:7 249:24 250:15 250:18 261:17 265:12 278:22 299:18 313:17 jeffery 3:9 jersey 1:1,16 3:4 jessica 27:9,14 28:2 job 141:2 283:23 john 1:11 4:3 7:12,19 31:15 31:21 32:21 39:8 421:2 johnson 1:3,3 9:2,2 35:6,7
---	---	---	--

[johnson - know]

Page 39

107:20,20	justified 67:17	194:21 196:7,8	know 12:1
109:20,20	justify 148:21	196:9,19 198:1	14:22 18:5,24
110:9,9,13	232:19 312:11	199:15 200:7	19:13 22:3
159:19,19	312:16 321:13	202:2,22 203:9	26:14,17 28:14
198:3,3 200:12	322:9	203:20 209:1	28:20 29:18,21
200:12 236:14	k	222:7 228:5	30:2,3,5 31:1
236:14 404:8	k 2:13 146:8,12	233:6,6 240:6,8	31:21 32:15
johnson's	kate 414:2	254:2 255:23	33:14,18 34:7,9
110:13 404:8	415:17	257:6 258:12	35:22 36:1,2
journal 11:14	kathryn 2:18	270:4 281:16	37:23 38:16,24
60:10 63:5	katie 4:17 62:6	286:14 294:13	39:1,2 46:4,5
69:19 71:3	62:14 128:18	298:21 302:10	46:11 48:17
75:18 108:15	129:1,23 137:4	303:19,20	49:8 55:10 56:8
108:23 109:9	137:7	304:19 311:17	59:22 60:7
109:14 137:12	keep 31:3	312:2,21 316:9	62:13,14,16,19
161:19 162:5,5	264:18	316:11 317:10	64:7,17 66:8
165:7,11 169:6	kelley 37:8	321:5 330:1	67:6 68:7,10
169:14 174:9	39:22 40:2 41:3	334:8 341:8,17	69:24 70:14
188:7 192:14	ken 70:7	343:11 347:10	73:3 74:18 79:6
197:20 217:21	key 358:24	354:10 356:11	80:2,15,23 81:3
218:6,7,13	kind 11:6,9	363:5 364:9	82:3,7 90:8
302:19 399:21	14:14 28:21	371:23 372:4	91:16 92:1,2
413:19	32:14 33:17	373:8 374:3	96:6 97:20 99:7
journals 163:7	36:8 40:1 46:11	380:9 390:18	111:16 114:13
jsco 197:22	78:19 84:22	403:18 407:21	118:9,13,14,22
199:13	86:15 101:3	409:7	119:5,7,8,10,13
juggling 125:3	102:18 103:9	kinds 73:20	120:12,13
july 1:7 109:17	105:23 106:6	80:16 135:24	122:6,6 123:20
199:11 418:7	122:18,19	149:11 268:11	123:20 125:1
jump 26:20	130:9 136:2	298:19 336:6	126:1,19,20
32:21	142:1,1 160:6	372:24	127:5 128:3,5
jumped 205:21	163:1,20	king 2:18	129:24 134:14
jumping 106:7	170:13 171:11	klehman 2:20	134:15,18
justification	172:16 173:4	knew 24:3	135:18,22
67:19 153:17	179:21 185:9	52:21 170:16	136:3,7 138:8
316:12		360:4	138:17,22

[know - lawyers]

Page 40

139:9 140:12	244:13 245:16	405:22 406:1	l
141:5 142:15	253:3,5,14	knowledge	l 1:14 418:15
142:20 144:4,6	258:3 259:16	13:24 66:19	labeled 269:19
144:10 149:17	262:2 263:11	104:16 107:6	lack 66:1 67:11
149:19 150:3	267:12 271:10	107:24 124:19	67:18,19
150:11,12,14	274:13 279:4	183:6 194:4	251:17 377:7
150:24 151:1,6	281:3 284:6	338:9	lady 27:10
151:12,15,20	286:17 291:21	knowledgeable	laid 106:17
154:20 159:6	303:13 307:24	85:10 92:9	lancet 154:3,3
159:17,18	308:19 310:18	known 34:10	157:18 193:4
160:7,13 161:1	317:16 324:4	300:8 386:24	415:24
163:1 164:6	325:4 326:3,24	knows 135:20	language 51:11
165:10 167:4,6	327:22 329:15	kornak 1:11 4:3	75:15
168:21 169:8,8	330:22,24	4:8 7:12,19,20	large 11:22
169:10,16	331:6,12,17,18	10:5,19 19:24	12:2,3,4 83:23
170:13,20,21	334:22,22	29:11 61:8,20	104:2 227:13
170:23 171:3	335:20 337:23	82:14 83:16	381:12
171:15,19,23	339:24 340:10	112:17 113:17	largest 388:4
172:18,24	341:13 342:17	114:22 115:24	late 371:6
174:12 177:23	344:10 345:21	117:10 120:6	372:19 374:18
182:10 183:22	346:20 350:17	123:4 125:18	393:12
185:7 190:13	350:23 351:4,6	129:2 130:24	latham 38:6
190:13 192:6	352:24 353:10	133:18 136:17	39:16
192:21 194:14	355:15 357:21	146:3 149:23	law 2:2,7 3:2
196:9 198:4,7	360:23 362:14	165:24 173:24	36:5,18 37:5,6
198:18,23,24	363:1 366:20	182:18 191:16	37:8 38:21,23
200:2 203:14	379:24 381:3	193:21 215:11	39:3 41:1,24
203:21 204:5	381:18 384:15	239:11 299:8	405:16
204:15 209:8	385:19 386:11	315:24 374:24	law.com 3:5
210:17 212:2	386:13,20	407:7,9,10	lawsuits 416:11
212:10 217:18	387:2,3,6,7,21	408:10 414:11	lawyer 18:14
218:8 219:4	389:20 390:2	414:17 416:1	326:24 334:14
220:12 225:8	390:23 391:15	416:17 421:2	lawyers 9:2
227:23 230:20	393:11 395:4,7	kslaw.com 2:20	16:3,9 17:23,24
231:7 232:21	397:8 398:24		18:18,22 19:1,7
236:20 244:11	401:2 404:12		

[lawyers - level]

Page 41

20:13 21:2,13	31:13 32:20	151:5 152:4,23	350:18 352:17
22:20,24 23:15	35:9 36:10 39:7	155:9 156:2	354:22 357:19
30:12 35:7	42:3,15 43:5	157:20 159:1	362:1 370:20
40:18 44:2,4,10	44:7 45:1 47:10	159:16 160:3	394:2 395:16
49:2 52:22,23	47:19 48:15	161:21 162:23	396:18 397:13
53:19,21 54:5,6	49:7 50:20	164:12 170:19	398:4 399:12
54:11,13 55:6	52:11 53:4	172:1,8 174:11	400:22 401:16
58:9 59:10	54:15 56:13	177:2 179:18	402:10 403:8
61:20 72:20	57:9,24 58:11	180:24 191:12	404:2,10 405:2
79:24 82:7,16	59:3,14 61:16	191:21 194:13	405:17 406:14
82:21 90:4	62:1,11 63:16	196:4 198:19	406:20,24
120:20 145:4	64:5,23 65:17	199:23 200:16	407:5,8 408:2,9
158:20 393:21	66:11,23 67:8	201:5,13 204:4	409:22 410:8
399:10 404:1,8	68:15 69:5	205:5 207:5	411:2,17 414:3
lead 129:12	70:10 71:6 72:3	210:10 221:10	414:7,20 415:1
154:23 353:20	72:10 74:12	222:23 225:6	415:19,21
leading 34:11	75:6,20 76:9	226:10 231:5	416:6,16,21
leads 238:10	77:3,22 79:3	232:10 233:4	417:1
358:7	81:14 82:12	236:18 237:13	letter 5:10
learn 79:14	88:8 90:6 91:8	240:13 243:14	69:18,23 70:3,8
357:2	91:15 93:8 97:9	246:19 251:24	70:13 71:2,9
learned 17:15	97:19 98:22	255:15 256:7	110:11 116:17
leave 55:1,2,3	100:20 101:16	257:2,12,22	117:9 190:16
leaves 309:3	102:3 107:10	258:18,22	201:9 386:15
led 223:7	108:1,17	267:16 268:18	letters 70:22
leeway 374:7,7	109:10,21	273:1 280:10	117:3
left 213:16	110:15 111:6	283:15 291:1	level 101:4
249:8 250:1	112:10,24	292:1 293:3	167:20 289:9,9
302:22 359:4	117:19 118:11	294:5 296:15	289:10,17
legal 20:7,19	119:21 120:21	302:6 303:2,22	305:5,5 352:22
27:1,5,8 28:22	121:14 122:15	312:24 317:5	353:3 357:23
121:12,18	123:2 124:22	319:21 320:21	363:4 368:5
lehman 2:18	126:17 127:23	322:20 323:1	384:9 394:5,11
4:4 15:18 16:23	138:13 139:18	329:14 343:21	395:5 396:15
18:9,15 21:4,19	140:11 143:10	345:4,14 346:2	397:21
23:18 27:2 30:6	144:17 145:6	349:23 350:7	

[levels - longer]

Page 42

levels 13:12 67:15 197:23 202:19 227:22 231:16 282:6 286:16 344:22 368:2	likely 211:24 212:3 213:21 215:18 216:13 225:4 226:3 272:5 332:22 337:15 348:21 367:1,21 397:6	lists 60:22 62:7 342:10 literature 85:4 89:19 91:1 92:16 95:13 96:10 97:7 99:10 104:8 109:19 110:3 115:14 117:16 147:6 184:16 184:18 218:9 290:24 291:4 295:3 316:16 400:6	193:13 223:14 238:14 244:15 248:1 262:6 264:17 266:5 278:21 315:18 319:8 338:23 339:1,5 341:20 378:20
levin 2:2 levinlaw.com 2:5	limit 280:21 limitations 149:3 302:1 355:23 357:5,7	litigation 1:5 16:4,13 17:16 22:13,14 23:6 23:16 24:4 31:17 33:10 34:2 35:21 40:10 45:10 51:22 53:2 56:12 63:15 68:3 72:1 78:12 79:20,21 81:22 83:3 107:7,19 107:22 120:11 120:20 121:5,9 124:19 143:5 198:1 203:3 405:16 406:13	living 183:10 llp 2:12,18 36:23 37:9,20 llt 9:2 locate 54:6 342:8 located 342:9 405:12 locates 54:12 location 1:12 locator 35:18 log 316:23 318:20 logic 309:7,23 337:13 logistic 254:11 343:13
li 299:3 liability 1:5 life 203:16 lifespan 284:9 284:11 288:24 lifetime 203:12 203:24 207:4 207:16 212:17 212:20 213:20 216:12 217:11 220:1,4 221:20 225:3 227:19 228:3,12 262:24 272:4 277:6,16 278:13 283:14 287:11,13 288:3 290:5 295:16,17 296:21,21,22 359:11 380:22 381:1,8,16 382:10,15 likelihood 360:14 363:8 400:7	limited 213:18 277:5,23 278:10 292:22 333:14 lindquist 37:14 line 6:5,8,11 74:16 81:3 82:3 104:22 247:14 365:4 420:4 lines 136:22 137:1 linked 291:6 318:16 list 29:4 30:8 132:4 194:16 194:22 315:6,7 342:16 413:18 414:11,13 415:6 listed 29:23 39:4 59:18 183:23 listen 108:13 207:12	little 14:15 19:16 21:7 29:2 51:11 112:12 136:23 163:23 164:1 172:16	long 14:5 31:2 98:1,1 118:24 200:4 235:18 341:12 352:19 359:24 383:13 383:14 longer 13:9 30:24 112:12 202:11 369:20 399:1 415:16

[longitudinal - magical]

Page 43

longitudinal 356:13 longitudinally 141:18 look 19:8,15,17 19:18 23:1,5,6 30:15 34:13 56:9,14 57:11 60:20,21 65:19 72:15 128:10 128:18 134:17 134:20 135:16 141:18 144:22 147:21 149:11 152:22 153:19 153:20,23 154:1 166:9 173:10,12 174:20 175:3 176:15 178:13 181:8 182:13 183:3 190:6 199:1 210:24 214:6,13 218:23 223:17 226:13 227:11 228:7 235:17 239:20,21,22 239:23 241:24 245:24 246:2 247:17 249:3,4 249:16 256:5 263:14 265:19 273:3,17 282:10 283:20 287:16 292:5	298:23 299:23 306:1,2 308:16 312:13,17 316:24 320:11 320:20 321:12 323:3,13,17 324:2 325:3,5 332:8 335:15 336:10 355:1 356:7,9,22 357:15,17 358:22 364:11 364:12,13,23 365:8 371:15 371:21,22 378:2,4,9,12,14 378:18 379:14 380:13 382:22 383:18 385:19 387:14,18 399:16 406:8 412:6 looked 17:11 56:7,8,15,16,20 56:22 57:7,11 57:13 96:7,7 113:6 119:15 119:23 133:2 142:8 146:4 152:8 153:7 167:19 212:5 218:21,23 238:3,19 244:8 245:21 248:11 248:12,19 258:5 274:13	277:20 317:9 320:23 321:4 331:16 344:5 352:9 353:5 383:19 386:14 387:20 393:19 395:22 399:10 400:19 413:3 looking 29:17 34:2 35:20 45:19 48:24 79:6 87:9 92:8 94:16 119:18 119:19 168:11 169:10 209:18 223:15 235:16 247:15 251:18 251:19 254:8 254:20,24 260:17 265:23 278:17 279:10 279:17 314:5 326:7 333:12 358:14 363:3 376:21,24 382:20 385:6,7 402:14 looks 10:16,17 49:23 215:7 288:23 loop 314:13 325:8 334:7 368:20 loose 51:11 86:6	lose 123:12 losing 308:12 lost 176:2 lot 53:11 84:11 85:21,22 97:14 103:18 107:21 109:20 117:16 140:15 163:2 182:9 244:12 286:11 308:14 308:14 369:12 372:10 381:21 397:17 413:4 love 173:8 low 341:19 360:12 384:7 lower 55:23 56:5 282:19 318:22 384:2 384:12 389:12 m m 2:8 made 28:22 33:17 65:13 66:19 109:20 109:24 128:5 128:14 130:12 167:16 175:1 196:24 237:22 263:15 283:24 306:6 375:23 419:7 magic 355:13 magical 365:21
---	---	--	--

[magnetic - mean]

Page 44

magnetic 94:5	387:10 396:1	182:17 191:15	134:21 136:4
magnitude	402:15	193:20 215:11	mdl 1:3 2:16
394:6	manipulate	299:8 315:24	mds 119:24
mailed 153:22	304:1	414:16	mean 13:18
main 129:16	manipulated	marketing 1:4	19:11 26:14
186:8 310:3	371:20	markings 9:24	30:11 33:19
358:19 359:4	manipulation	10:2 11:2,4	34:21 37:22
360:1 377:24	234:15 236:5	mas 1:4	40:11 41:22
378:1,3 380:1	262:21 303:7	massive 341:15	44:14 45:2
major 163:19	303:20 347:7	378:23	48:16 49:10
372:7	349:5 355:11	match 245:12	51:10,24 53:6,9
majority 96:20	376:10 400:15	246:12 353:16	54:18 65:7
219:2	manipulations	matches 34:3	68:10 73:14
make 9:12 10:9	238:2 268:5	matching	74:13 76:17,24
12:20 73:22	283:4 289:11	246:11 353:14	78:1 79:5 80:20
99:1 102:16,17	298:20	materials 72:23	81:15 85:21,24
155:17,17	manipulative	93:10 140:15	87:18 92:11,18
160:22 163:21	238:10	145:11 190:8	95:20 97:20,22
172:10 182:6	mantel 131:8	405:4,9 413:17	99:6 105:1
216:2 217:7,13	march 166:13	414:10 415:5	106:23 107:12
244:1 261:8,12	margaret 2:8	math 139:23	122:17,19
265:23 271:14	margaret.tho...	279:6 325:1	126:3,18
286:3 296:2	2:10	353:22,24	132:23 139:7
313:4 330:3	marginal	mathematically	139:20 141:16
332:16 352:15	390:21	325:1	142:12 143:11
359:22 371:19	marked 4:7	matter 121:12	145:7 150:6
372:10 373:2	6:10 10:4,19	268:8 291:12	153:2 159:5,6
375:11 382:20	19:23 24:12	418:7	162:24 165:9
384:13 419:4	29:2,3,10 83:18	matters 27:11	167:8 169:19
makes 25:15	112:16 113:16	255:23	170:12 179:19
220:14 224:23	114:21 115:24	maximization	182:8 183:18
265:24	117:10 125:18	147:23	185:6,24
making 76:5	129:2 130:24	mcar 96:15	186:24 190:12
101:4 157:9	133:18 136:16	mcdevitt 3:2	194:15,23
177:21 302:23	149:23 153:23	md 4:19 133:12	197:14,15
303:1 305:14	165:23 173:24	133:14,17	200:3,18

[mean - methods]

Page 45

203:19 222:1	means 60:18	members	80:16 185:3,18
226:9 227:18	127:6 177:17	150:13 183:19	186:22
231:16 238:18	177:19 187:17	memory 20:16	methodological
245:16 248:18	194:19 223:24	55:13 265:16	130:9 323:14
257:4 265:19	251:1 330:15	278:15 416:1	methodologic...
268:4 270:4	418:23	menopause	130:5
285:15,16	meant 334:3	227:5,6	methodology
287:22 292:2	395:11	mention 204:8	60:3 95:16
295:20 301:1,7	measure 14:13	mentioned	164:24 166:23
303:12 304:10	353:13	102:24 124:7	180:17,18,20
306:11 308:16	measured	146:5	180:22 181:5
308:19 309:14	340:21	merely 39:12	188:11 197:10
311:12 312:18	mechanism	merit 69:4	291:11 316:15
312:20 314:21	36:1 185:1,17	merlo 200:11	317:23
317:20 320:16	377:18 378:9	mess 286:21	methods 13:2
322:11 323:3,8	mechanisms	message 380:1	57:22 58:3 59:5
326:22 327:18	171:16	met 16:3 19:6	66:9 73:23 76:7
328:24 330:13	media 252:24	21:2 23:15	76:11 84:19
331:3,5 332:14	416:12	27:13 28:2,8	86:14 93:19,20
334:13 335:9	median 113:2	45:8,24 49:2	95:7 96:1 97:8
336:2 341:24	medical 34:11	52:23 55:6 58:8	97:12,24 98:4
344:11 346:19	85:3 87:17,21	61:21 399:9	98:11 106:10
347:19 349:11	87:22 128:9	meta 56:17,22	107:23 108:3
351:15,20,22	253:6	57:13	108:11 132:21
353:11 357:1	meet 20:18	method 13:14	146:6 147:7,17
360:16 361:6	26:24 27:4,8	64:21 93:21	147:19 149:12
363:2 371:14	28:5 45:21	94:2,20,22	150:13 167:22
374:15 377:18	meeting 16:8	100:7 101:13	175:5 177:11
378:16 379:21	19:5 20:6,18	102:5,9 148:14	177:16 178:6
381:4 390:1	22:5,12,23	290:22 291:3,5	195:12 196:2
391:13 398:5	27:14 28:9 50:4	293:20 302:4	198:5 199:2
398:24 415:17	53:19 54:11	309:19 316:10	201:23,23
meaning	110:10 404:8	317:21 322:6	211:1 229:9,12
177:10 233:15	member 127:13	333:24	230:6,22
234:9 235:13	127:15 129:6	methodologic	232:19,20,23
390:20	150:10	58:7 73:22	241:20,22

[methods - model]

Page 46

242:1 292:11	202:9 258:14	231:12,13	148:15 290:20
299:1 300:20	259:2 415:20	233:14 234:7	293:21 296:6,9
301:1 302:16	mischaracteri...	238:12 262:19	298:7,19
312:19,22	231:9	269:7 275:7,18	301:15 303:16
313:2,14	mischaracteri...	276:12 280:5	304:7 308:3,21
318:19,22	304:10 307:1	280:18 281:9	311:2,16,21,24
mi 305:15,16	misclassificat...	281:12,23	327:7 338:13
mice 96:13	186:15 195:13	289:9,13,20,23	338:22 340:6
336:12,20,21	357:9,9 360:15	290:2,5,11,14	341:22 359:14
337:7	375:13 376:1	290:15 291:5	359:16 362:19
michelle 2:13	misleading	294:18 295:7	363:5 367:17
mid 109:17	364:8 370:19	295:21 296:23	misstates 53:5
199:11	mismatch	297:18,18,23	mistake 311:9
middle 152:13	354:1	298:5 299:3,24	mistaken
260:6 373:22	misread 395:11	300:5,6,17,21	395:24
midnight	397:12	301:14,15	misunderstan...
398:23	misreporting	305:5,9,19,23	280:12
million 137:23	375:15	306:9,10,16	mixed 337:18
138:10	missed 164:24	307:8,9,11,16	mixture 394:12
mind 68:11	165:7,10	307:20,22,23	411:7
97:17 99:15	166:20 167:1	308:17,20	mixtures
108:14 111:13	179:13 182:13	311:23 312:4	115:18
122:10,22	186:22 219:15	318:4,7 320:6	model 48:13
128:20 159:5	230:1 344:19	320:18 325:18	187:21 297:22
160:14 164:23	395:13 400:20	326:12,13	304:19 309:10
202:10 258:10	400:24	327:9,13 330:9	310:1,6 311:11
269:10 313:17	missing 94:17	333:17 334:9	312:8,12
380:14 392:8	94:18 96:12,13	335:3,5,11,17	313:21 314:15
minds 401:3	96:13,14 97:22	336:7 337:11	316:7 318:8
minimal 86:20	100:8,10,11	337:22 340:23	319:5,17 320:5
minute 69:18	101:21 103:18	344:22 354:8	320:5 321:18
94:8 141:10	104:2 105:4,5,5	354:11,14,24	325:17,17
202:3 207:24	106:13 147:18	355:5 409:11	326:17 330:16
320:12 405:19	148:2 149:2	missingness	331:23 332:19
minutes 140:9	215:20 229:1	93:22 94:3 96:6	334:1,4,6,17
145:17 161:2	229:16 230:10	103:22 147:8	335:24 336:22

[model - needing]

Page 47

342:22 343:5 343:12,23 344:7 384:10 modeling 146:13 187:18 187:19 330:18 409:20 models 326:11 371:17 392:14 modest 173:3 394:6 modify 141:22 moment 17:14 19:4 22:9 28:16 33:8 46:3 153:20 161:6 165:21 212:10 266:3 328:20 392:4 monday 1:7 money 107:21 109:20 120:19 monographs 4:23 149:21 montgomery 2:9 month 89:19 200:23 months 11:18 166:15 210:14 211:13 221:13 246:10 274:9 283:20 381:7 motives 70:15 125:1 198:6 231:11	mountaintop 203:10 mouth 374:11 move 12:23 15:12 101:8 110:4 123:15 124:11,15 149:7 155:3 164:6 197:7 199:8 202:22 222:13 224:10 224:20,21 259:13 333:18 333:20 412:17 moved 153:5 moving 193:14 mparfitt 2:15 mri 146:12 multiple 13:4 48:11 52:5,6 64:19 65:13 87:14 91:20 93:18 94:1 100:3,6,9,17,22 101:12,18 103:3,16 104:9 104:23 105:2 105:10 117:21 119:20 148:13 149:1 151:21 186:12 189:11 189:14 202:18 227:22 229:24 234:1 235:24 236:6 269:7,13 269:20 289:21	290:21 291:2 291:11 293:19 295:5 297:3,19 299:2 301:13 302:2,4 304:18 305:16 306:16 306:21 308:8 310:16 311:8 311:13 313:13 316:6,14 317:22 318:2,3 320:17 321:18 322:2 326:10 328:21 330:21 335:3,11,16,17 337:20 338:18 339:10,18 340:15 341:7,9 343:4,14 349:6 354:20 355:7 399:21 408:18 multiply 394:22 multivariable 343:7 n n 4:1 94:10 418:1 n.e. 2:19 n.w. 2:13 name 7:18 27:11 34:1,6,23 46:3 114:7 116:6 133:4 134:12 192:24	199:20 302:19 names 132:5 151:11 naomi 183:22 narrower 263:12 national 125:12 131:22 132:16 133:11 168:6,7 169:20 413:7,8 413:19 nature 7:5 nearly 183:8 nebulous 179:22 necessarily 31:2 necessary 419:4 necessity 219:15 need 18:5 77:5 147:2 161:8 172:23 202:23 206:10 207:12 220:21 249:19 255:18 266:4 284:15 286:3 308:6 319:18 319:19 322:24 334:19 340:5 354:2 372:9 406:14 412:1 413:23 needing 188:4
---	---	--	---

[needs - number]

Page 48

needs 84:2 86:10 162:13 negative 189:18 200:8 negligible 379:22 neither 17:20 298:16 nelson 319:4 nervous 32:14 105:23 neuman 36:23 41:4 never 18:4 42:4 62:17 64:1,17 64:21 80:19 90:19 99:15 124:18 128:19 139:15 154:5 158:6 213:8 276:9 279:19 281:19,22 303:17 304:15 312:1 337:8 364:17 365:10 367:2,3 368:15 369:5 383:15 394:9,15 398:10 399:10 404:17 new 1:1,16 3:4 153:9,9 173:16 202:2 318:22 359:11 373:13 newly 359:8,12	news 90:9 399:14 newspaper 90:11 nicolas 4:19 114:4 133:9,17 niehs 126:9 130:19 131:17 173:16 night 416:20 nih 4:12 9:4 11:22 12:7,9 58:22 59:12 61:22 75:16 76:7 108:16,20 109:7 110:24 117:15 118:6 119:16 120:7 121:3,11 124:18 125:9 125:13 126:2 126:22 127:17 130:16 135:4 158:22 163:13 168:19,21,22 169:4,7,10,18 169:23 170:10 170:16 171:2,6 171:7,13,18,22 172:6,18 173:10,14,24 174:10 175:4 179:16 180:20 190:4 197:21 199:13 212:10 236:15 264:5	290:19 351:10 399:19,24 400:4 403:3 nine 166:15 254:15 267:5 267:13 268:17 noise 339:3,17 non 88:1 254:9 254:13 337:18 340:20 354:10 371:23 383:14 noncontradict... 270:7,9 273:10 273:21 nondifferential 360:14 nonresponsive 101:9 124:16 199:9 224:11 nonstatisticians 302:22 nonuse 280:8 337:24 nonuser 189:19 270:12 273:4,7 279:12 292:12 292:21 293:23 295:5 296:18 338:12 354:7 354:12 355:3 nonusers 269:24 279:8 280:9 284:21 290:1 292:24 295:16 296:12 305:1 336:23	337:11 397:5 normal 17:16 17:21 18:7 54:3 69:11 170:8 norwood 131:8 notary 1:15 421:20 note 305:15 notebook 412:5 noted 7:9 351:24 399:15 419:11 421:8 notes 11:6,7,8 11:11 49:24 50:3 418:6 notice 155:1 notoriety 199:12 200:5,7 null 318:22 327:19,19,24 328:1,7,8,8,11 328:14,16 331:1,1,20,24 333:18,20 358:2,7 number 4:7 12:3 72:15 146:7 158:3 168:1,3 184:2 214:20,21 222:16,17 254:3,6,16 258:5,11 267:20,21,22 276:11 279:4 314:21 336:11
--	---	---	--

[number - object]

Page 49

347:23 348:2	108:10 111:14	230:5 243:24	48:15 49:7
361:3,13,23	113:7,12,16,21	246:3 248:13	50:20 52:11
362:11 367:20	114:16,21	248:14,16,17	53:4 54:15
371:3 379:10	115:8 116:10	249:13,18	56:13 57:9,24
380:5 387:22	116:14 117:4,9	254:22 255:1	58:11 59:3,14
392:20 394:24	120:9 121:4	255:11 260:4	61:16 62:1
numbers	128:18 129:1	262:7 265:7,13	63:16 64:5,23
210:22 215:1	130:6,12 132:3	269:9 278:18	65:17 66:11,23
219:5 223:17	137:4,7 138:5	307:9 309:22	67:8 68:15
223:19 231:18	141:1,7 142:13	333:8 351:10	70:10,11 72:3
255:23 265:8	142:23 144:3	354:3 358:14	72:10 74:12
265:21 278:16	145:9,10	358:15,22	75:6,20 76:9
298:11 330:2	148:20 149:5	362:13,22	77:3 82:13 88:8
360:11 361:11	149:12 151:1	375:4 376:9	90:6 91:8,15
394:22	154:18,21	377:17 382:9	97:9,19 100:20
numerous	155:1,6,23	382:12,16	101:16 102:3
58:21	156:7,16 157:6	385:8 386:13	107:10 108:17
nurses 142:11	157:15,16,17	387:17 391:3,3	109:21 110:15
143:24 356:3	158:12,13,14	399:20 400:5	111:6 112:10
o	158:19 159:9	400:13 401:19	112:24 117:19
o 418:1	159:10,12	405:8 406:8	118:11 119:21
o'brien 4:16,17	161:3,14,17	410:2,14 411:3	120:21 121:14
5:1,9,10 9:11	163:14 167:24	411:10,18	122:15 124:22
10:4,13 11:1,13	173:15 174:18	412:4 413:3,5	126:17 127:23
11:21 16:5,18	179:5 181:9	416:8,9	138:13 139:18
20:5 22:14,17	187:14 188:2	o'brien's	140:11 144:17
23:21 24:22	192:19 195:7	129:16,23	145:6 151:5
26:6 52:22 55:5	195:11 196:1,3	155:7 156:1	152:5,24 155:9
56:9 57:12,23	197:16 201:22	276:6 309:18	156:2 157:20
58:2 59:18	201:24 203:5,5	379:6	159:1,16
60:22,23 62:7	203:6 213:15	object 15:18	162:23 170:19
62:14 64:4 70:6	215:21 218:17	16:23 18:9,15	172:1,8 174:11
70:9 71:15	220:14 224:7,9	21:4 23:18 30:6	177:2 179:18
92:20,24	224:14,22	35:9 36:10 42:3	180:24 191:12
107:23 108:8	225:21 226:22	42:15 43:5 44:7	194:13 196:4
	226:23 228:24	45:1 47:10,19	198:19 199:23

[object - okay]

Page 50

204:4 205:5	322:20 323:1	offering 97:5	65:5,10 66:24
207:5 210:10	350:7,18	offhand 104:13	71:1 72:8 73:8
221:10 225:6	401:16 402:10	offices 3:2	73:12,19 74:3
226:10 231:5	407:19 408:7	oftentimes	75:12,14 78:4
232:10 233:4	409:18 410:5	291:24	78:10,22 79:17
234:12 236:18	410:23 411:15	oh 38:4 105:1	83:9 84:8 87:8
237:13 240:13	416:5,14	133:14 137:7	87:24 88:20
243:14 246:19	objective	165:3 174:22	90:16,24 91:4
251:24 255:15	358:19,24	174:23 190:4	93:24 94:19
256:7 257:2,22	359:4 360:1	231:6 232:20	95:10 96:6
267:16 268:18	objectively	251:9 272:12	101:23 102:8
273:1 280:10	353:6	285:15 323:14	102:13 104:7
283:15 291:1	observation	329:24 380:15	107:4 108:7,14
292:1 293:3	301:2 306:12	okay 7:23 8:10	109:16,17
296:15 303:2	observe 381:13	8:15,17,24 9:11	110:6,23
312:24 319:21	observed	9:13,21 10:23	111:24 113:4
320:21 329:14	375:17 394:5	11:12 12:5	114:4,14 115:2
343:21 345:4	409:9	13:15 15:2,5,6	115:11,17
345:14 346:2	obvious 363:6	16:2 17:13,19	116:4,9,13,14
349:23 352:17	400:20	19:3 20:4,14	117:14 118:3
354:22 357:19	obviously 49:21	22:8 24:15	118:18 119:15
362:1 370:20	205:14 263:6	25:21 26:4,11	121:2,8 124:9
394:2 395:16	285:17 309:2	27:7,13,20	125:22 126:5
396:18 398:4	395:13	28:10,13,15	127:8,16,21
399:12 400:22	oc3 4:22 134:2	29:15 33:7,9,23	129:22 130:13
403:8 404:2,10	136:11,16	36:7,15,16 37:7	131:5,21
405:2,17	388:5	37:13 38:5,9,20	132:10 134:7
objection 21:19	occasion 45:23	39:2,15 42:10	136:9 137:4
27:2 62:11 71:6	occur 300:5	43:13 45:6,15	138:4 139:10
77:22 79:3 93:8	occurring	46:5,13,21 47:3	142:6 143:3,4
98:22 108:1	250:22	48:24 49:14,20	144:8 145:18
109:10 143:10	odd 369:17	50:13 52:8,20	146:17 147:15
164:12 191:9	offer 9:3 50:18	52:21 54:2 55:4	148:3 149:7,15
191:10,11	57:20 73:14,16	55:17 56:6 57:2	150:23 158:17
200:16 201:13	263:9	57:3,18 58:5,20	161:1,4,9,11,14
302:6 317:5		61:2 62:6 63:24	161:15 162:19

[okay - opportunity]

Page 51

165:5,16 167:3	247:21 248:14	366:4,5,21,22	onus 240:23,24
170:16 172:13	249:6,19,23	368:3 369:2,14	open 115:22
172:20 174:4	250:13,18	370:10 374:8,9	opened 8:8,9
174:16 175:3	251:19 254:20	374:13,17	operating
177:24 179:10	254:21 255:3	375:3 382:19	18:22
179:13 180:13	256:12 258:6,9	382:23 383:18	operation
180:14 182:7	260:16 262:5	386:20 392:16	406:2
182:15 183:13	262:16,22	393:1,6,18	opining 95:18
185:14 186:4,7	264:1 265:15	394:18 395:2,9	145:1
186:21 190:1	266:11,17	396:19 397:11	opinion 9:9
192:10 193:5	268:7,10,23	404:23 407:6	25:23 26:1
193:12 194:9	270:10 274:3	408:3,18,24	42:20 43:1,3
195:9,23	275:6,22 276:4	409:4,15,23	51:20 57:20
198:14 199:12	277:12 278:2,5	410:9 412:9	67:5 100:2,3
200:3 203:8	278:6,14	413:12 415:8	143:9 144:16
204:10 205:2	280:21 281:15	415:14,22	192:1,8 198:16
206:23 208:13	284:10,16,17	416:7,16	287:3 302:10
209:4 210:5	284:24 285:1	old 111:20,23	302:12 325:7
211:5,15,21	286:14 288:6	210:8,19 211:2	390:1 403:22
212:9 213:1,3	289:4 293:18	211:7,10,16	opinions 9:3
213:14 214:2,7	293:22 297:10	219:13,13,19	48:22 50:7,10
214:8 215:15	300:3,15,19	221:5 227:4	50:11,17 51:1
216:7,24 217:5	301:24 302:14	292:23 293:14	60:19 63:22
217:7,20	302:21 303:21	oldest 211:16	65:5 71:16,19
218:16 219:7	304:21 305:8	omission 155:1	71:24 73:14,16
221:17 226:20	306:5 309:12	omits 276:11	73:17,18 95:14
227:9 228:23	310:3 313:8,18	once 286:7	96:16 97:2,5
229:8,12	316:4 321:3	oncologists	98:17 110:19
230:14,15,21	325:11 329:5	182:4	153:13 154:23
231:7 232:16	334:4 335:6,13	oncology 11:15	162:11 182:11
233:10 234:5	337:3 338:3	182:23 183:5,8	366:20 404:4
235:2,6 236:4	339:6 341:18	183:9 197:21	404:23 407:11
237:2 241:21	342:21 344:10	402:4	407:14 408:14
242:6,11 243:2	349:20 351:9	ones 78:23 95:2	opportunity
243:7 244:3	355:15 363:7	95:23 189:10	324:14,16,18
245:24 247:6	364:5,14 365:8	408:23	325:14

[opposed - overreporting]

Page 52

opposed 64:20 87:3	311:10,17 312:8,11	88:20,22,24 89:2,8,11,20	314:6 337:10 347:17 359:9
opposite 273:9 334:19	314:13 316:22 318:11,17,21	90:3,13,21 91:24 92:13	359:19 370:3,5 371:1,3 373:7
opt 82:3	319:12,17,19	112:2 116:15	375:6,17,20
options 222:6 223:6 246:15 263:10	320:5 322:10 325:18 326:8 331:22 332:19	117:17 118:8 122:12 129:19 133:23 134:1	377:1,11,21 379:3,7 381:15 383:9,12 388:7
order 19:17 29:2 84:3 103:11 119:17 244:1,9 330:10	333:3 338:10 338:18 340:20 342:24 359:10	134:10 135:17 137:10,16,18 137:20,24	388:24 390:23 391:23 392:13 396:8,11
organization 150:17 183:17 186:10	outcomes 48:12 137:19 313:22 317:13,22,22 318:15 321:17	140:8,18 142:9 151:24 152:1 152:18,19 156:8,11	399:11 401:14 401:24 403:6 410:4 411:13 411:19 412:12
organized 139:6	322:3,19,24 335:8 336:9 347:8	158:16 173:19 186:12 188:15 192:22 193:8	413:2,13,20,21 414:22,23 415:10
original 85:15 142:16 211:22 212:13,19 215:17,19 219:13 220:23 221:8,23 225:1 263:20 270:19 283:13,17 285:5 286:7 292:24 303:14 419:14	outer 280:6,21 281:4 outline 181:12 315:19 outright 42:8 outset 283:12 outside 79:24 80:5 83:2 107:7 107:22 110:8 171:16 197:24 198:21 298:3 404:19 407:17	194:5,17 195:16 196:23 197:5 203:13 203:18 204:2 204:14,17 205:1,13 207:1 208:6,16 209:12 212:18 233:17,21 234:10 235:19 237:11 250:3 251:4 252:6,15 253:4,7 260:12 261:22 262:11 264:8 265:3 266:10,13 267:7,14,24 279:15 308:18	ovaries 383:5 overall 12:2 77:16 78:7 178:1 196:8 255:23 262:8,9 266:9,13 279:8 279:14,18,21 300:17 319:3 354:7 378:11 383:20 391:23 393:3,23 395:15,19
originally 105:18 284:20 286:12	outweigh 222:10 223:13		overcome 306:17
ought 285:21	ovarian 13:7 14:2 24:20 25:12 55:21 56:2 57:7,21		overdoing 105:16,17
outcome 103:6 105:11 122:11 298:3 309:9 310:16,18,21			overreporting 413:1

[overstating - paper]

Page 53

overstating 75:4 own 48:21 86:24 96:10,15 96:18 98:16,20 190:23 191:1 216:16,19 282:22 285:9 357:6 372:12 375:11 379:6 390:2	233:1 235:17 235:18 239:23 241:9,14 242:14 247:1,4 247:15 249:3,5 249:14,21 250:14,15,15 250:16,17 260:5,5 261:9 261:15,17 262:6 264:18 265:13,13 266:2 269:8 278:18 299:6 302:1 309:21 313:8 320:3 321:24 332:16 338:16 358:22 359:3 361:17 363:24 376:24 379:16 380:7 381:11,12 383:2 387:21 387:22 392:8 392:19 393:13 412:6 420:4 pages 166:5 421:3 paginated 387:24 paid 16:21 17:1 38:3,4,9,11 72:8 107:21 110:13 124:19 168:24 198:2 198:14 199:19	200:12 201:11 346:8,9,14 405:1,1 panel 150:10,14 151:3,12,20,23 152:21 panels 151:16 papantonio 2:2 paper 4:15,16 5:4 9:10 10:4 10:17 11:21 13:23 14:20 15:4 16:18 17:10,10 20:6 20:12,24 21:10 21:18 22:18,21 23:21,23 24:1 26:18,23 42:1 42:14 43:3,11 43:22 44:5 49:2 49:6,19 50:3,8 51:20 52:2 53:1 53:10,13,16,22 54:3,4,8 55:8 55:16 56:6 57:8 57:11 58:14,23 59:6 60:10,13 61:3,5 62:21 63:4,7,9,10,21 64:10,12 66:15 67:11,18 68:12 71:14,17,20,24 72:5 73:15 75:17,23 76:8 78:14,20 80:10 80:18 81:7,9,23	82:7,10 86:4,13 90:23 93:19 94:15 98:11 99:5 108:14,19 108:21 110:2 110:10,12,19 111:10,17 113:10 116:24 122:10 123:17 123:23,24 124:1 125:2 132:13 133:5 134:12 136:8 138:8,19 140:9 142:23 153:5 160:21 161:5 162:9,10,17 163:19 165:15 167:7,16,19 169:4 170:18 173:5 174:19 174:21 177:13 178:6,10,12 179:6,15 181:11 183:14 184:10 185:10 185:11 188:7 190:12 192:15 192:17,19 193:14,20 195:2,7 196:1 196:11 197:17 197:22 198:11 199:11,14,20 199:22 200:14 200:21 201:12
p			
p.c. 3:3 p.m. 417:8 page 4:2 6:5,8 6:11 13:24 23:7 24:16,16 25:2 26:19 30:18 36:17,19 39:21 60:21 61:3 117:5,5 126:5 129:10,10 131:5 133:22 134:21,21 154:1 155:22 156:4 160:23 168:4,10 183:4 183:15 188:12 204:11 209:19 211:1 213:2,3 213:15 214:23 215:1,6 216:5,6 217:1 218:17 218:20 226:24 230:4,11,12,23			

[paper - parts]

Page 54

207:7 210:17	papers 41:18	320:13 338:15	385:14,16
210:21 214:4	43:10 44:22	359:21 361:17	participant
220:16 226:13	46:24 48:5,7	362:3 375:1	210:1 213:8
229:4,10	49:12 56:7,8	379:9 380:4,7	265:1
230:17 231:12	57:12 62:17	412:6	participants
232:6,17 235:3	68:23 74:10	paragraphs	254:4 305:23
236:16 245:15	77:20 79:1	322:12	371:14 381:5
245:19,22,23	91:20 92:13,16	paraphrase	411:5
247:20 249:5	92:18 93:4 94:4	196:10 197:16	participate
278:19 287:22	96:18,22 97:15	197:18	42:8
288:5,9,13,18	97:21 111:24	paraphrasing	participated
288:20 299:12	117:21 123:19	179:5	121:11
302:3,20 303:6	138:23 147:18	parfitt 2:13	particular 14:9
312:9,14,15	147:20,21	parroting	23:13 32:6
314:19,24	148:5 172:15	177:12 178:9	56:16,17 73:15
315:1,6,7,11,15	172:21 180:8	178:12 179:16	85:8 87:20 89:6
315:23 316:4,8	203:15 237:22	199:16	103:4 111:1
317:1 320:15	344:11,16	part 23:12 32:3	148:22 151:3
320:16,19	407:22	35:23 48:12	156:21 159:11
321:12,16,23	parachuted	54:18 93:19	204:1 206:18
322:10 323:14	194:4	101:9 113:7	209:5,5 240:9
324:2 325:2,4	paragraph 25:1	116:5 138:5,10	352:14 353:9
325:10,14,22	25:4,7,18,19	138:16,17	364:9 396:5
333:9 334:13	51:16 68:2,5	139:1,8,13,15	403:12
342:2 344:8	75:2,8 156:5,18	140:21 142:13	particularly
345:9,13,17	158:4 175:10	142:16 147:24	13:8 43:22 82:8
351:20 352:7	176:13,16,19	151:2,22	84:5 91:14,18
353:7 363:4,14	195:11 204:11	155:19 158:11	91:19 162:7
375:14 382:11	242:15,21	194:20 205:14	165:1 176:22
388:4 392:5	260:6,6 262:8	230:1 252:12	184:5 186:16
393:15,20,24	264:4,15 266:2	252:16,21	390:4
395:6 396:5	275:23 276:5	257:7 266:7	parties 7:1,8
400:19 401:5,6	292:5 300:4	291:7 310:1	partly 333:15
401:7,20,22	302:21 305:12	311:6 314:15	parts 49:21
402:17,18	309:7,14,16	329:17,18	308:7
404:13 407:24	313:12,17,18	330:17 339:14	

[party - perfectly]

Page 55

party 40:3	164:22,23	118:6 122:7	242:18 243:2,9
pass 363:10,11	165:6 166:19	127:4 135:21	243:12,16
363:19	167:15 169:5	135:24 138:24	244:20 256:22
passed 217:16	169:11,12,15	162:4 172:15	256:24 258:5
229:17 230:16	170:8,15 174:8	177:15,17	263:22 264:7,8
230:17	179:13 180:15	178:5 179:4	265:2 266:18
passing 363:16	184:24 185:7,9	180:22 182:9	266:24 267:3
past 56:12	185:12,15	183:10 184:8	267:13,18,22
127:9 150:24	190:3 197:20	184:19 196:22	267:23 268:4
151:19 161:1	200:24 202:18	198:21 207:21	268:13,16
210:14 221:13	217:16 218:9	219:8,9 223:22	279:7,14,15,18
399:22	229:17 230:16	235:10 243:9	279:21,21
patency 383:3	230:17 236:16	248:20 251:2,3	353:18,18
patent 382:21	245:16 363:10	252:9,24	354:1,7,9
383:7 389:1	363:11,14,16	256:23 263:11	361:22 362:4
390:4	363:19,21	281:22,24	362:11 364:16
path 216:3	399:21 400:6	284:20 285:7	365:9,9,15
pathway 383:4	400:17,18	286:11 304:14	366:24 367:5,5
patient 259:20	401:7	307:15 308:21	367:9 368:5,14
patients 231:20	peg 294:22	310:23 344:12	368:23,24
279:2	pejorative	352:9 365:17	369:3,9,11,12
patterns 115:3	101:2	369:13,17,17	369:13 372:2
pause 7:6	pending 158:21	370:13,18,19	378:11,13,15
pausing 12:8	pennsylvania	370:24,24	389:8 394:9,13
pay 172:23	1:16	371:23 376:18	394:20,24
peachtree 2:19	penny 120:10	people's 182:10	396:17,21
peer 11:14 13:5	120:19	perceive 192:18	397:2 398:1,8
63:4,5 66:22	pensacola 2:4	192:19	412:13,14
67:1 75:17 76:8	people 34:14,15	percent 47:23	percentage
104:5 106:22	45:24 46:16	90:8,17 156:12	243:21
108:15,23	49:11 61:9 70:1	157:12 164:2,2	perfect 109:5
109:4,8,13	70:22 83:8	196:15,16	241:3 311:21
110:1 115:13	91:12 96:17	227:5 231:15	perfectly 283:6
122:3 160:17	99:6 100:18	231:15 233:17	308:6 311:15
161:18,24	106:11 107:12	234:10 235:13	311:24
162:1 163:6	109:19 111:18	237:11 242:15	

[perform - point]

Page 56

perform 313:15 320:17	personally 111:3	pieces 26:21 86:20 302:12	183:15 191:5,5 201:5 213:3,4
performed 64:2 64:8,13 67:16 176:21 196:2 318:8,13 407:16	perspective 16:19 17:3,6,9 17:12 21:18 80:8 88:2 143:2 183:16,16 186:9 228:10	343:9 345:7 347:6 pinpoint 95:22 pitch 172:17 place 71:23 72:4 73:13 264:16 285:22 286:22 372:22 403:21 404:3	249:17,24 260:5 261:17 264:17 278:22 279:10 299:17 315:20 318:2,3 319:8 336:12 419:3,8
performing 345:8	phd 1:11 4:3,17 4:18,20,21 7:12 125:17 129:1 129:24 130:1 130:17,23 133:12,15,18 134:22 136:5 421:2	placed 7:23 places 264:3,4 placing 85:10 plain 187:22 plaintiff 2:15 plaintiffs 2:5 2:10	plenty 53:14 68:21 69:2,9 plot 47:6 plus 280:5 349:5
perfusion 146:12	phds 46:12,19 119:24	plan 66:13 67:12,20 141:20 286:1	point 20:22 41:19,23 46:4 75:12 81:17 98:9 99:19 103:11 104:18 124:17 134:14 139:21 145:14 145:20 156:12 156:18,24 165:1 170:7 175:7 187:24 197:3 198:9 203:24 204:18 204:20 234:21 243:22 248:15 253:15 258:14 261:6 265:17 267:17 271:20 282:20 285:24 305:18 306:9 307:18 312:16 316:9 317:10
period 58:16 204:1 211:10 211:19 213:21 217:10 221:12 223:20,23 225:4 226:2,5 272:5	phone 28:6 184:2 phrase 42:11 44:3,18,20 45:4 74:24 289:6	plausibility 375:18 plausible 14:3 282:12 365:6 384:3 388:20 388:22	
periods 186:18 213:18 216:10 216:13 220:13 227:13 278:13	physical 80:21 383:4	play 330:2 373:10	
peripheral 73:20	pick 167:20 picked 165:14 201:19	playing 95:11 pleadings 158:20 please 7:6,17 7:18 65:8 83:19 123:4 139:12 154:2 158:4	
permeated 296:8	picking 165:13		
permission 40:18	pie 265:17 piece 26:22 51:17 187:1,1,6 187:6 248:16 302:10 323:20 379:13		
person 12:6 28:6 135:19 183:21 194:7 208:8 260:8 261:18			
person's 127:7			
personal 3:6 115:18 392:12			

[point - predictors]

Page 57

326:16 333:12 334:19,24 338:14 339:16 341:8 347:19 348:15 356:10 361:3 362:15 364:6,18 365:13,18 367:6 371:4 377:24 378:1 382:4,23 388:16 389:5 390:7,9 393:21 394:19 pointed 200:24 252:12 384:20 pointing 156:20 249:11 260:24 353:17 points 263:18 307:16 378:3 pontificate 285:18 pooled 113:6,11 154:6 158:7 193:8 383:23 388:14 poor 295:24 poorly 298:17 pop 97:17 population 352:14 377:5 portion 278:3 position 22:21 104:9 122:21 125:23 126:20	127:22 128:14 184:15 251:20 252:2 285:17 positions 126:3 128:17 positive 14:11 15:15 25:9 78:8 79:14 154:4 155:6 158:5 189:9 252:10 260:13 261:10 261:23 262:10 349:16 352:11 364:15 367:4 367:22 368:16 386:22 387:9 387:11,13,16 388:6,13 389:2 390:3,5,10 391:8,12 positively 14:1 186:11 250:2 possibility 164:23 237:5,5 284:19,23 379:1 410:22 416:13 possible 82:5 125:4 149:4 153:6 176:9 178:24 206:21 213:7 272:13 387:9 possibly 333:15 353:13	postdoc 127:5 postmenopau... 250:5 378:14 394:10 potential 24:21 32:11 176:7 178:22 186:14 187:16 188:5 197:1 222:10 227:24 237:19 238:20 240:2,3 244:10 252:20 255:4 275:3,4 275:17 284:1 288:15 328:18 329:10 341:22 347:24 348:7 348:18 351:11 359:20 361:19 361:23 375:4 389:18 390:19 potentially 126:19 228:17 270:3 292:7 301:8 powder 1:4 56:2 90:21 193:7 195:15 203:23 210:13 233:18 234:11 375:6,19 377:10 383:5,8 383:12 388:7 401:14 powered 134:2	practice 105:21 106:5 232:18 302:11 320:7 325:19 334:15 340:8 practices 1:4 pre 42:21,24 250:4 precise 14:23 15:8 25:1 353:13 372:21 precisely 245:6 precision 360:13 predict 102:10 106:10 292:11 292:15,18 293:9 311:24 320:6 325:18 331:7,13 337:24 338:12 338:21,22,24 predicted 331:14 predicting 339:4 prediction 137:19 predictive 297:22 298:4 336:21 predictor 103:2 104:11 predictors 103:18 298:3 339:9 340:14
---	---	---	---

[predictors - product]

Page 58

340:21 343:4 predicts 355:2 preeminent 158:22,23 159:6,13,14 285:24 preferred 356:24 391:4 preliminary 202:24 premenopausal 378:19 premise 282:7 prepared 49:24 50:17 78:24 preparing 16:4 50:3 51:14 58:9 72:23 405:5 present 3:8 14:14 38:7,14 82:9 364:10 presented 79:23 80:4 president 127:9 prespecified 66:2,13 67:6,12 67:20 141:20 press 151:8,19 415:23 416:2 presumably 128:16 154:16 pretends 341:6 pretty 55:14 61:2,4 73:16,19 77:21 89:16 125:22,23	126:15 223:18 323:9 372:5 prevents 80:13 previous 33:16 34:18 39:20,21 123:19 153:18 211:13 272:7 323:22 359:8 375:8 previously 29:8 155:21 158:19 183:2 237:22 260:24 313:19 322:1 324:21 primary 88:3,6 88:16 103:2,6 104:11 105:11 principle 183:6 printed 157:18 prior 36:17 89:18 90:24 120:9 155:8 156:1 213:6 227:5 274:9 380:6,11 385:5 387:18 priori 65:14 66:9 383:6 prioritize 99:4 privileged 22:6 31:20,24 32:4 32:16 33:3 39:14 82:21,24 probability 305:18	probable 151:24 152:18 153:7 probably 43:7 52:17 165:12 278:16 339:7 389:22 probit 343:13 problem 81:20 101:21 136:3 167:12 202:4 212:14 226:15 270:22 288:21 294:13 295:22 295:23 296:17 298:21 306:16 310:24 313:3 324:7 326:15 327:15 341:4,7 351:23 353:8 354:18 355:7 355:12 362:23 363:17 412:3 problematic 199:3 225:12 238:8 305:6 problems 43:11 44:17 53:16 55:15 74:20 98:6 124:2 165:15 167:21 185:10 187:6 187:12 198:9 198:10 214:15 218:5 222:9 227:24 275:3	275:17 288:19 296:7 306:24 350:21 355:8 360:3,8 361:24 362:12 363:22 400:14 401:6 402:18,20 procedure 330:18 336:13 336:20,21 368:22 proceedings 121:18 418:4 process 50:11 51:14 63:4 109:5 110:1 151:15 160:17 162:1,19,20 163:3,5 164:22 166:15 169:9 170:13,14 171:4 184:24 185:16 201:1 202:18 229:19 235:23 304:20 311:5 329:7 331:8 339:18 340:11 343:11 349:19 363:21 processes 130:11 236:11 produced 22:19 23:4 123:16 125:2 product 115:18 189:22 205:18
---	--	--	--

[product - published]

Page 59

206:18 213:17	proportion	360:10,18	154:3 160:6,17
216:9 224:23	223:9,11 233:8	361:1,12	165:17,23
346:15 359:6	257:8 308:20	380:11 381:13	166:11,13
392:12	308:23 371:10	385:10 388:5	168:4 170:9
production 6:7	411:21 412:19	398:11,18	173:13 182:17
products 1:4,5	proportional	prospectively	199:21 384:18
3:6 9:5 175:14	392:14	248:21 333:13	publications
175:20 176:8	proportionately	357:7,24	44:22 88:24
178:16,24	353:19	protocol 141:24	95:22 104:5
195:14 242:8	proportions	prove 241:1	134:16 151:22
247:10 248:5	67:14 231:22	proved 241:6	153:10 154:16
259:18 411:6,8	279:7 307:13	provide 16:17	169:2 193:2
professional	351:18	33:17 41:10	386:21 408:19
1:14 46:16,20	proposition	42:13,20 64:14	publicly 70:21
83:22 84:4	15:14	340:22	publish 122:10
121:13 418:15	propositions	provided 29:20	169:4 404:18
professionally	96:11	40:12 43:3	published
111:4,8	propounded	46:14 54:4 55:4	11:19 16:7 42:1
professionals	421:6	83:17 104:6	43:3 47:17,22
183:9	proprietary	243:9,10	63:5,10 75:17
professor 34:10	338:10	375:14 376:2	88:21 95:13,17
34:12 134:15	pros 288:15	provides 61:6	108:15,21
346:9,13,16,19	prospective	173:16 185:1	109:7,13 110:2
410:2,12	68:1 124:4	188:13 219:5	117:16,21
profile 4:22	129:13 137:17	377:8 403:4	121:4 137:11
136:16	141:6 157:6,8	providing	147:6 148:11
program 104:1	195:17 198:11	103:5 242:18	158:20 161:18
168:6	244:8,22	243:3 317:21	166:14 172:5
project 72:21	248:22 250:23	406:9	173:5 184:16
86:9 384:6	251:8,13,15,20	proving 240:24	184:17 188:8
promise 179:11	251:21 252:6	public 1:15	192:14,22
366:16	253:2,18 255:3	70:24 109:18	199:11 200:22
proof 240:19	261:11 276:2,8	200:15 203:22	217:20 230:18
properly	283:24 348:9	205:3 421:20	287:9,10
100:23	352:10 356:24	publication	288:12,13,17
	357:3,6 360:8	4:13 5:8 95:5,6	316:16 353:7

[published - question]

Page 60

399:20 400:5 408:20 413:18 publishing 76:8 115:13 118:7 118:13,16 194:9 195:1 pull 83:18 390:17 392:20 pulled 139:5 165:16 231:23 purely 32:24 67:24 purpose 22:12 51:22 321:19 purposes 97:4 310:24 pursue 69:22 put 34:6 63:12 69:17 134:12 154:1 172:15 172:22 199:19 230:21 231:1 278:19 322:12 325:15 333:21 puts 33:24 321:10 putting 31:22 85:2 122:20 334:20 405:6	160:20 161:10 161:13 qualified 105:14 120:1 147:5 188:6,9 355:22 qualifier 300:18 318:12 qualifies 14:15 270:20 qualify 15:21 147:2 262:17 310:15 319:10 338:1 qualifying 79:7 qualitative 13:17 quantitative 9:6 13:3 20:5 64:2 163:12,22 164:8,15 175:23 176:6 176:20 178:21 195:18 197:11 229:2 230:7,12 230:24 233:2 329:8 330:8 347:6 359:15 quarter 145:15 question 6:10 21:6 23:11 28:1 34:24 36:12 54:18 55:4,19 57:17,17 61:19 62:24 63:2 64:21 65:2,3	67:7 68:24 69:7 74:9 84:17 89:12 90:18 91:11 92:6 93:3 94:13,13 95:24 97:13 98:10 102:9,11 107:17 108:13 109:3,6 110:7 118:19 120:15 138:16 140:22 141:11,14 142:7,9 143:14 143:15,18 144:5,14 146:24 147:4,4 147:5 148:4,10 152:9,14,22 155:4 157:5 161:9 164:7,8 180:6,12 182:6 191:3,13 197:8 197:9 199:10 199:18 200:4,9 200:10 203:21 204:3 205:10 206:1,10,13,14 206:24 207:11 207:13,13,14 207:19 208:5,7 208:11,15,18 209:6,9,10 212:6,15 215:16 220:22 221:22 222:14 222:15,20	224:13 228:2 229:15 230:2,3 234:4 237:18 240:10 241:18 242:14 244:7 244:16,21,24 245:3,6 246:4,5 246:15 247:1 248:12,21 251:21 257:17 261:19 262:24 264:2 267:9 268:3 270:18 270:23 272:9 272:10,14,22 284:15 285:2,3 286:5,15 288:4 289:1 291:7 293:11,13,21 294:11 295:10 296:6 297:2,8 298:15 304:6,7 306:3 312:18 312:21 313:2 327:2,3,5,6,22 328:20 329:1,4 329:10,12 330:6 337:14 342:18,20,21 351:1,8 352:19 353:3,6 366:18 373:18,23 374:2 380:4 381:4 390:19 391:1 400:3 405:20 406:19
q			
qualification 203:20 qualifications 119:16,23 128:16 149:10			

[question - ratio]

Page 61

406:21 407:4 410:13 413:4 417:2 questionnaire 5:2 106:13 119:7 142:17 142:18 143:7 209:21,24 210:12 211:8 211:17 212:14 212:19 213:5,9 213:10 214:14 215:3,8,10,17 215:19 216:8 217:2,8,11,16 217:19 218:10 218:11 219:14 219:21 220:10 220:23 221:8 221:18 222:16 222:17 223:4 225:1 227:12 227:13 228:14 228:20 229:14 237:7 239:17 241:19 242:3,4 245:4,5,11 246:9,11,14 251:2,3,5 255:14 256:21 256:24 257:20 260:9,20 263:1 270:2,13,19,20 270:24 271:17 271:18 272:2 275:12,13	276:17,20,21 277:15,15 278:10,12 283:13,18 284:4,19 286:8 286:10 287:18 288:14 289:5 290:4 292:21 293:1 303:15 303:17 348:10 348:11 351:13 351:14 356:4 412:16 questionnaires 92:7 119:4 141:13 217:24 244:19 247:8 248:7 285:14 356:8 questions 58:21 59:2 60:3,7,13 61:23 62:10 63:6 65:11,16 65:20 68:23 69:10,17 71:1 95:21 143:6 144:11 186:6 202:24 206:22 208:17,22 213:17 214:20 214:22 216:9 221:8 223:5 224:23 228:6 228:15,22 232:8 244:12 246:12 251:21	258:17,19 259:13 263:10 271:11 277:4,8 285:11,23 286:4,8 294:16 294:19 329:13 353:15 356:12 379:9 399:3 407:10 413:13 415:15,23 416:18 421:6 quick 83:10 325:3 quickly 110:1 326:7 quietly 323:22 quite 85:21 141:4 157:13 188:1 189:7 228:11 237:15 238:15 360:16 367:8 369:10 369:10,11 385:13 395:2 396:20 quote 68:8 176:3 271:19 quotes 291:23 quoting 178:12 r r 418:1 420:2,2 rafferty 2:2 raise 63:14 68:22 69:10 228:15 284:22	raised 58:21 raises 192:6 284:19 285:3 random 96:13 96:14,14 105:5 105:5,6 290:17 297:19,23 298:2 301:2 305:9 306:10 307:13 326:12 326:13 334:9 335:5,12,17 336:7 341:3 349:19 355:6 360:24 361:1 randomly 264:24 range 14:2 85:24 86:5,6 139:24 165:14 189:21 210:18 211:22 263:14 280:6 282:12 375:7,12,24 ranges 367:7,9 ranging 234:23 rarely 306:6 rate 73:8 rates 14:4 rather 77:13 137:7 316:11 379:3 ratio 156:9 157:11 233:15 234:8,22 250:3 261:6 310:6
--	--	--	--

[ratio - recall]

Page 62

314:16 327:23	272:1 284:1	164:17 170:21	130:3 132:13
328:22 329:9	305:12 309:6	172:19,24	132:19 134:8
330:10,23	320:12,15	173:6 174:19	135:14 138:20
331:10 347:4	322:11 323:15	177:16,23	139:11 153:12
347:16 348:13	323:22 324:15	179:6 180:10	153:16 167:9
348:19 352:11	324:16,21,22	181:22 185:8	167:13,17
364:16,19	334:18 393:15	185:21 190:15	214:5 267:23
367:4,8 368:16	393:16 395:10	200:4 202:20	288:4 290:18
372:22 373:12	396:4 416:22	203:21 208:1	341:13 395:24
373:13 380:18	419:3 421:3	208:11 209:4	419:5
380:21 381:9	reader 375:11	218:1 223:12	reasonable
383:20 384:1	376:3,5,5	229:5 238:17	204:22 298:10
386:7 389:5	reading 25:1	243:11 255:16	303:9 308:4
391:5,23 393:3	26:17 45:7	255:22,24	312:19 349:12
393:24 394:14	89:21,22 90:10	258:13,16,18	375:12 408:16
394:20 395:15	90:22 111:16	258:20 267:8	reasonably
395:19 397:20	176:12 177:5	268:19 269:15	348:20,24
ratios 236:22	192:19 247:20	272:10 276:22	reasons 290:3
237:19 384:19	323:6,8 334:13	282:9,12 285:6	343:1 377:17
385:20	334:15 405:4	285:21 296:5	reassign 365:10
reach 59:11	ready 8:22,24	302:9 320:10	369:4
63:3 184:3	real 153:12	324:20 328:21	reassignment
384:8	171:11 209:3	329:12 330:6	365:20
reached 26:1	240:5,8 306:23	338:20 341:23	rebuke 77:21
61:22 236:15	339:2 410:21	347:7,13 349:8	recall 13:5,13
reaching 184:8	realistic 362:12	351:1,7 361:4	13:14 14:19
read 15:7 17:11	362:15 375:12	362:17 368:24	15:16 16:8
26:12,15,19,22	375:24,24	369:10 371:18	27:10 28:7,12
49:2,3,5,9 87:9	reality 286:6	372:10,24	43:17 45:3,22
87:10,11 89:19	really 22:6	384:13	48:1 50:9 52:12
90:19 91:1 96:7	60:11 61:12	reason 12:10	53:7 56:20 66:5
100:16 156:22	73:21 75:13	19:12 23:3	66:6 67:16 68:4
177:7 190:14	85:20 123:11	43:23 62:8 80:9	68:5 87:6 88:23
190:14 198:22	125:5 127:4	95:10 98:14	89:9,21,22
234:5 245:15	141:4 142:3	122:1 123:21	90:22 93:15
245:18,22	160:10 163:24	126:4 129:22	104:12 114:15

[recall - regard]

Page 63

132:22 142:24	358:18 359:20	recent 151:9	redoing 245:17
144:7,21 157:8	360:10 361:20	381:19,23	reduced 260:11
158:23 174:23	362:11,16,24	382:8,12 385:6	261:4,20
177:19 179:7	363:8,9,23	416:11	reevaluate
189:15 195:21	364:8 366:1	recently 381:14	359:5
197:11 207:7	367:19 368:1,5	reception	reevaluating
218:2 221:21	368:8,18,21	160:18	360:5
223:7 235:1	372:5,7,9,12,24	recess 83:13	reevaluation
237:3,8,20,23	374:5 376:14	145:22 202:14	188:5
238:11,20,22	377:6,9,19,22	259:5 324:9	refer 99:20
239:16 240:2,5	378:10,13,15	374:21	112:5 156:4
241:6,9,18	378:23 379:5	reclassification	215:21 266:1
242:16,23,24	379:17,23	196:13,17	267:10 292:7
243:11,19,23	380:2 382:1,2	reclassifying	391:20 392:1
244:10 247:9	384:23 386:18	195:20	reference
248:4,18 251:8	389:18 390:12	recognized	143:23 321:6
251:10,14,17	395:8,20 400:7	100:7,10	references 97:1
251:23 252:20	401:13 410:20	101:13,19,23	154:15
254:21 255:1,6	411:12 412:22	135:11 290:23	referencing
255:22 260:10	412:24 416:10	recollection	99:5 317:11
260:19 261:3	recalled 35:6	19:10 20:11	321:12
261:20 262:3	35:11 242:9	recommend	referred 146:15
262:19 264:10	259:19	319:3	215:20
269:1 277:2,19	recalling 35:12	reconstruction	referring
283:24 288:15	411:6	94:5,8 146:9,12	190:19 248:17
292:3 299:14	receipt 419:15	record 7:10,18	368:4 389:5
304:17 312:10	receive 54:2	8:19 9:19 10:24	392:5
329:11 330:1	128:15	34:23 35:3	reflect 83:22
347:1,9,24	received 54:8	146:2 147:12	reflected 27:21
348:3,13,18,21	77:17 78:22,24	147:12,13,16	50:18 64:3
349:3,7,15,21	116:23 120:10	148:7,9 214:13	254:16
350:2,4,12,14	120:17 127:16	324:15 330:7	refresh 19:9
351:1,12,18,21	134:21 165:19	recorded	20:10 278:15
352:3,7,8,15,22	166:11	290:12	refreshes 20:16
353:1,14,21,24	receiving	recruit 86:19	regard 296:6
354:4,5,13	403:24		

[regarding - report]

Page 64

regarding 25:14 112:1 352:1 400:7 registered 1:14 418:15 regression 254:11 318:6,8 343:13,14 regroup 259:11 regularly 46:1 reilly 3:2 reinforce 310:20 reject 328:11 rejected 162:18 relate 305:17 related 9:6 11:9 46:12 87:21 89:10 90:13 92:19,20,24 94:4 96:3,23 103:1 129:18 129:18 176:10 179:1 204:1 216:9 224:24 292:16 311:16 340:20 341:21 346:21 348:21 359:7 379:9 405:8 409:14 416:11 relates 84:5 268:20 relating 9:3 22:14 88:4 89:14,20 90:2	90:20 185:3,18 391:1 relation 92:3 relationship 19:1 36:2 85:19 90:20 154:8 158:9 347:16 393:2 406:4 409:5 relationships 340:18 relative 69:4 331:3,4,5 365:11 393:22 relatively 297:13,16 304:12 release 151:9 151:19 415:23 416:2 relegated 67:23 67:24 68:8 124:8 276:1 relevance 14:13 192:15 257:16 relevant 65:4 99:10 278:23 325:10 reliability 44:15 115:4 144:15 251:22 376:23 reliable 56:1 154:24 158:15 197:3 208:14 241:2 275:23	298:11 373:6,9 387:12 reliably 56:4 228:11 401:23 reliance 315:6 315:7 relied 143:5 184:14 320:17 320:19 395:6 relies 82:9 309:22 rely 316:5 384:24 relying 124:2 190:24 291:18 371:17 378:8 remember 14:23 20:17 65:16 112:23 132:4 149:13 149:14 155:10 239:12 258:4 264:12 278:15 299:16 332:9 387:1 remind 168:1 212:7 214:11 215:23 244:23 393:8 412:1 remote 1:11 2:1 3:1 7:5 remotely 7:3,4 removed 8:13 removes 81:22 rendered 325:7	rendering 67:4 82:18 renders 66:2 repeat 21:5 23:11 53:24 68:24 83:5 230:2 239:10 repeated 310:4 repeatedly 155:5 291:19 291:21 rephrase 55:3 57:17 61:19 91:10 100:4 102:8 107:17 143:13,17 180:2,5,12 200:6 206:1 237:17 266:22 329:4 337:14 400:3,10 replace 300:22 replacing 301:15 report 4:9 10:11,16,19 11:1,10 16:4,13 16:22 17:2 22:13,20 23:2,7 23:8,17,22 24:3 24:8,11,16,17 28:3,9,16 29:1 32:13,19 39:5 40:15,20,21 44:20 45:10 47:4 48:4,21
--	---	---	---

[report - response]

Page 65

49:18,24 50:4 50:12,15,18,23 50:24 51:3,4,6 51:8,12,13,13 51:14,23 52:16 52:19,21 53:2 53:23 58:10 59:1,11 63:15 65:11,21,24 68:3 72:1,6 74:23 75:2,14 76:18,20 77:18 78:11,12,14,16 78:18 79:17,20 79:22 80:3 82:18 92:3,14 93:4,10 96:7,21 99:17 100:1,16 136:11 152:6 153:1 155:4,19 155:22 166:24 190:7 198:8 203:3 204:9,12 209:20 213:8 234:19 256:17 257:17,18 258:1 264:3,14 264:19 265:17 265:20 276:5 276:18 287:20 288:19 290:8 291:20,24 309:8,21 310:5 315:11 317:4 336:11 345:8 349:21 361:16	364:6 373:4,5 375:5 377:9 386:2,3,4 391:22 396:3,6 396:7 397:19 399:18 400:12 402:16 403:22 404:5 405:4 407:12,15 408:15 reported 59:5 64:9 115:4 154:6 158:7 175:19 219:6 234:17 250:20 255:20 256:19 256:23 257:10 278:9,9 280:8 285:10 286:12 377:3 395:13 reporter 1:14 418:15,24 reporting 7:6 176:8,9 178:23 179:1 186:14 187:16 195:19 245:19 257:20 260:18 377:20 411:5,22 412:13,14 reports 44:23 157:15 279:9 represent 287:13 356:1 representative 228:12 340:6	381:8 representing 93:12 represents 183:8 381:9 reproducibility 358:10 reproducible 64:15 reproduction 418:22 reproductive 186:19 383:7 reputable 150:16 request 6:7 47:14 48:20 183:24 416:24 requested 46:24 required 162:15 326:10 383:3 requires 306:8 rerun 105:22 research 18:1 18:19 30:19,23 36:8 46:22 48:11 54:4 61:10,13,23 69:11 71:2 77:21 85:10 86:24 87:16,20 93:7 96:16 98:17,20 126:9 135:8,10	141:14 149:18 150:8,22 168:5 172:17 188:4 204:3 205:8 209:5 212:15 299:24 399:16 researched 30:2 researchers 120:2 133:24 reserve 164:5 resided 267:5,6 268:2 resolution 95:8 146:10 resolve 185:12 resolves 185:8 resolving 185:2 185:17 resonance 94:6 respect 45:9 81:2 82:4 104:23 105:4 105:11 133:23 134:10 139:16 140:24 150:18 170:24 188:10 respective 85:18 86:4 119:11 respects 277:23 respond 70:4 167:14 224:12 290:4 response 5:10 116:16 117:2,9
--	---	---	--

[response - reviewing]

Page 66

154:8 158:9	244:17 256:2	reveal 32:1	26:12 62:20
242:19 243:3	260:7 291:18	revealing 31:20	63:1,5 75:17
281:14 285:20	301:12 331:8	reverse 384:11	76:8 93:13
386:15 387:7	331:23 358:8	reversed 206:6	104:5 108:15
responses	370:15 371:16	412:11	108:23 109:4,8
116:20	372:17 384:11	review 11:9,14	109:13 110:19
responsibility	385:3,4 388:12	16:17 22:17	115:13 140:14
47:12 169:24	391:15 395:12	23:21,23,24,24	140:16 145:10
171:8,10 195:2	410:15	26:18 53:10	161:18 163:6
226:12	retain 30:11	57:4 58:2,14	181:11 190:9
responsible	373:12	60:18 63:4,20	199:13 215:4
89:8 120:8	retained 9:8	71:14 92:23	217:19 218:9
159:20	19:8 23:14	106:22 107:1	236:16 245:7
responsive	30:12 38:1,15	110:1 122:3	245:16 399:21
62:15	38:20 40:4 54:6	136:7 145:9	400:6
restating	80:22 81:21	160:17 161:24	reviewer 60:18
256:14	121:5	162:1,8 164:22	167:15
restore 189:21	retracted 287:9	169:5,11,12,15	reviewers
restricted	retreat 305:21	169:16 170:8	66:22 67:2
383:10	retrospect	170:15 171:11	162:7,9,17
restrictive	355:20	171:12 177:11	164:24 165:7
306:8	retrospective	184:9,24 185:7	165:14 166:19
result 125:4	124:3 141:7	185:9,12,15	167:19 169:13
169:3 249:1	143:8 244:22	190:4,4,23	174:8 179:13
259:20 260:1	255:6 348:8,10	191:2 197:20	180:15 364:3
308:18 328:24	355:16,21,23	197:24 200:24	400:18,18
371:12 376:18	356:11,18,22	202:18,19	reviewing
376:23 384:14	356:23 357:1	217:16 229:17	26:10 41:17
389:11 390:16	357:10 360:7	230:16,18	50:3 53:12
resulting	361:2,8,9	256:16 325:14	60:10 62:16
360:12	384:22 385:15	345:9,17,21	72:23 162:10
results 86:14	389:17	363:10,12,15	169:17 170:24
105:24 106:3	retrospectively	363:16,19,21	180:8 226:13
155:5 175:16	285:18	401:8 407:24	227:16 404:13
178:18 230:22	return 419:13	reviewed 13:5	407:22
231:1 236:15		17:9 20:5 26:6	

[reviews - risk]

Page 67

reviews 185:9 401:2	165:13 166:4,8 166:20 168:18	280:23 281:2 281:17,21	346:11,12 347:13 349:10
revised 166:12	178:8 179:17	282:2,4 283:14	350:23 353:5
revising 51:6 51:13	180:13,23 183:3 186:19	284:13,21 285:6,9 288:12	354:16 355:24 357:12 360:15
revisits 175:13 178:14	187:10 188:10 189:2,5,18,20	288:16 290:6 290:14 291:14	361:5 362:24 363:5,10 365:2
right 9:15 10:23 11:12 16:21 18:21 20:22 22:2,9 24:11 25:19 26:11 33:15 34:4,20 35:1 38:17,18 45:13 46:2 50:2,6 53:18 54:10 57:16 62:10 63:6 69:14 70:19 71:22 72:18 78:23 83:9,16 86:17 87:8 88:3 91:23 92:21 97:18 102:22 105:8 106:16 111:12 112:12,21 113:21 122:14 123:14 132:6 136:9 137:1,2 141:9 146:21 150:11 152:3 152:11 154:14 156:1 157:13 161:16 163:9 164:20 165:5	190:22 197:19 199:6 201:21 203:6 204:3,18 205:3,4,10,20 206:4,5 209:8 209:13 211:15 214:3,16 217:3 218:16 225:5,9 228:8,13 231:4 232:9,24 234:18 235:3 240:20 242:12 243:21 246:23 248:7,10,12,13 248:23 251:5,7 251:8,14 254:21 255:11 256:6,10,24 259:8 261:1 262:5 263:21 265:23 268:10 270:15,16 271:2 272:6,11 273:23 274:12 274:22,24 275:9,15,17 276:2,13,15 277:6,13,18 278:7 280:17	292:12 293:2 293:17 294:3 296:24 297:12 297:20 302:14 302:19 303:1,5 303:18 304:8 304:21 305:1 310:2,7,8 312:19 313:13 314:6,8,10,16 314:18,20 315:2,10 316:17 317:3 317:15 318:11 318:15,18 322:8,24 325:8 326:24 327:5,7 327:18 328:4 328:17,24 329:13 330:5 332:18,23 333:2,19 334:7 334:14,18 335:22 336:23 337:24 338:6 339:8 340:7 341:9 344:14 344:14,20 345:3,12	365:5 367:19 368:2,3,12,16 369:12 370:11 370:13 372:3 382:10 383:2 388:18,23 390:1 391:12 395:1 397:24 398:3 399:8 403:7 407:9 408:22,22 410:20 411:3 416:16 rigor 198:1 rigorous 175:15 176:23 178:17 188:20 189:7 402:7 403:4 ringing 298:8 risk 81:10 88:15,17 89:6,7 91:12 103:10 129:15 134:3 134:10 135:16 137:18,19 150:18 157:8 173:18 186:12 188:15 193:8

[risk - says]

Page 68

196:23 203:12 204:2 234:10 235:12,14,20 236:2 237:11 244:2,2,4,5,5 252:8 253:8 255:4,6 280:24 281:4 311:17 330:10 334:21 348:21 358:1 364:16 365:11 367:4,7 368:16 369:6 375:17 383:13,20 385:9 386:17 388:7 393:3,23 395:15 403:6 413:20 414:22 risks 197:1 375:13 376:1 rls 1:4 rmh 3:5 robin 1:14 416:21,23 418:15 robust 384:12 402:5 role 28:23 86:8 86:22 169:21 245:9 413:9 416:2 roles 85:18 86:4 119:10,11,13 119:17 rolling 329:22	room 17:5,8 rothman 70:8 rough 416:24 417:3 round 294:22 row 266:7 278:24,24 279:1,10,12,18 332:7 354:6 378:4 rows 265:18 266:12,16 278:23,24 royston 5:4 314:23 315:23 317:16,20 322:5,14,15 324:13 332:16 334:4 335:1,2 336:5 343:2 rubin's 105:2 335:10 339:22 rude 258:13,15 ruin 283:6 rules 171:13 339:22 ruling 387:8 run 105:24 340:9 361:12 running 371:11 s s 2:18 4:6 94:10 s4 392:2,9 safe 305:21 306:5	safety 81:5 sales 1:4 172:17 sample 12:2 252:14,17 254:4,11 260:11 261:4,5 261:21 264:8 265:2 266:19 267:1,3 268:4 268:14 340:6 360:24 361:1 sampling 364:22 sander 4:18 125:17 sandler 114:1 115:9 116:4 125:9 126:6 136:21 137:3 138:5 159:12 161:3 saw 90:2,9 139:4 140:13 317:9 323:20 352:10 399:13 saying 15:23 25:18 28:11 31:9 80:15 81:24 82:1 98:15 123:12 123:23 130:1 141:2 155:11 157:4 164:4 172:22 176:1 187:10 192:4,5 204:20 218:14	223:23 227:10 227:21 243:8 247:21 254:6 255:2 260:21 273:17 274:1 281:13 288:10 293:5 296:13 303:6 304:4,22 305:3 306:1,4 310:14 316:14 316:21 319:11 321:12 334:15 341:18,20 343:5 348:15 349:13,15 351:3,5 352:20 354:11 355:5 363:1 366:6 367:21 368:9 368:12 382:2 386:18 387:12 390:2 391:16 391:17 397:17 403:15 says 13:24 23:8 26:6 30:14 51:3 126:6 127:8,16 129:11 131:5,6 131:14 133:24 135:2,8 137:15 154:2 155:15 157:18 158:5 160:9 168:4 173:15 175:9 175:10 176:4 188:13,19
--	---	---	---

[says - section]

Page 69

189:1 195:9	282:19 290:20	sciences 125:13	342:7 388:1
199:17 213:2	294:15,17	131:23 132:17	392:4
217:1 219:6,7	295:8,17,18	168:7	scroll 39:20
224:7 226:22	296:11 307:6,7	scientific 69:12	318:3
226:24 241:15	311:21 337:1,6	81:23 85:4	se 145:2
247:8 248:3	337:16 347:12	135:3 162:4,20	search 12:19
249:8,24	347:19 364:9	162:21 185:2,4	searched
254:22 259:17	364:15 365:24	185:8,17,19	343:17,18
260:7,15	366:1,23	186:6 246:4	344:3
270:12 271:17	367:15 368:8	408:16	seattle 131:16
272:1 274:15	368:11,13,18	scientifically	second 113:9
274:16,17	369:2 371:22	236:17 287:23	117:5 131:4
280:14,14,17	372:8,12,13,14	scientist 73:15	146:11 168:14
280:19 281:17	372:15,16,16	79:24 107:6,21	225:13 227:12
295:3 299:23	372:23 373:10	129:11 236:13	245:4,11
299:24 300:5	376:2 379:18	285:2,16	246:10,13
302:1,15,22	379:18,20,21	scientists 9:4	249:20 251:3
305:13 309:13	scenarios 13:5	58:23 61:22	254:3 255:14
313:18 315:15	14:3,20 15:16	68:22 69:3,10	256:21 257:20
317:1 318:1,14	64:3 186:13	75:16,22 76:7	260:19 263:17
319:18,23	195:20 197:12	107:9 108:16	264:1 271:18
320:3 321:24	231:2 238:3	109:8 118:6	272:2,9,14
323:9 325:15	264:22,23	120:7 121:4,11	275:6,12,13
325:15 332:16	282:8 295:23	124:18 163:13	276:10,17,20
335:16 336:16	349:8 351:19	169:4 173:16	277:14,15
352:1 359:22	361:18 363:9	200:13 236:15	282:9 284:18
362:23 375:3	363:11,23	264:5 350:24	290:4 303:17
375:10 377:1	373:11 375:14	351:11 399:19	326:16 329:9
381:12 383:2,3	school 126:14	399:24 400:4	348:5 360:2
388:4 391:22	128:9	401:11	379:12
392:9,10 394:4	schuman 37:15	scope 152:5	seconds 374:10
396:7	science 69:3	153:1 171:17	section 65:21
scan 324:18	75:23 104:1	screen 166:4,10	66:1,6 86:14,14
scenario 189:12	171:11 185:13	176:17,20	190:3 202:2
189:17,18,20	205:17 286:18	217:4 247:18	211:1 229:9
234:20 269:11		249:15 278:20	230:6,19 232:5

[section - serious]

Page 70

241:20,22	193:11 194:11	392:23 393:10	sends 162:6
242:1 309:8,17	198:7 211:1	393:12,14	senior 125:10
309:18,22	213:23,24	394:16,17	130:17 133:9
313:14 371:21	215:1 216:14	402:20,24	135:4
382:24 385:2	219:9 227:7,8	seeing 89:23	sense 32:4
387:15	231:3 232:2	212:22 249:15	40:23 46:23
see 10:14 12:23	239:18 241:19	377:22 387:1	51:19 85:23,24
20:8 26:8 34:13	241:23 242:10	seek 63:21	104:3 187:23
42:10 50:1 51:5	244:9 246:15	95:12 404:18	252:21 263:7
61:1 63:13 66:4	246:16 247:12	seeking 93:1	263:12,15
66:20 70:12	249:2,18	seem 160:9	332:3 374:3
75:5 96:9 98:13	250:15,23	320:8 334:17	sensitivity
98:14,14,15	262:13 265:4	seemed 21:6	106:2 149:5
106:18 114:2,6	266:10 268:20	seems 35:23	371:11,15
116:6 119:24	282:18 289:24	87:12 111:21	390:18
125:14 126:11	298:24 299:5,6	123:17 126:19	sent 7:24 8:3
127:11,19	299:22 300:9	225:21	80:5
128:20 129:8	300:10 301:4	seen 14:4 27:11	sentence 65:8
129:20 130:7	301:17,18	69:19 70:5 80:3	77:6 175:24
130:20 131:11	305:13 314:2	92:3 96:15,18	188:19 250:1
131:13,19	315:14 316:17	109:17 110:17	260:7 272:1
133:14 134:23	317:24 318:1	117:24 142:22	300:4 359:23
135:6,12 136:6	318:24 319:6	143:23 144:2	359:24 360:2,9
136:13,21	321:22 325:23	159:3 183:1	381:11
137:3,13 138:2	333:21 336:13	192:2 200:13	sentences 14:10
138:18 153:8	336:15 338:19	201:7,8 218:20	77:10 359:24
153:12,16	343:19 348:19	218:22 223:9	separate 20:21
154:10,11	353:12,22,24	299:12,15	41:5,7 231:19
156:5,6,14	354:6 355:1	326:6 360:23	327:13 329:12
158:17 168:9	358:20,24	393:24	329:16 374:4
168:16 169:19	365:3 371:15	select 264:24	separately
171:10 172:6	375:21,22	self 115:4 219:6	275:16
176:2,2 180:10	380:3,19	412:13	september
182:24 183:11	381:15 383:16	send 122:3	156:9 166:11
185:10 188:16	385:20 388:13	173:4 414:9	serious 58:7
188:17,23,24	392:3,15,19,20	417:3	79:2

[seriousness - slight]

Page 71

seriousness 415:18	shown 415:24	simply 46:15	211:5,7,16,21
serving 131:14	sic 382:9	105:13 163:21	211:22 212:4
set 20:18 66:9	side 21:16	295:4	212:11 215:10
103:7 164:9	41:11 81:5 83:6	simulating	216:17 237:12
225:23 286:19	120:11 177:18	341:3	262:23 287:14
294:16 298:8	249:8 250:1	simulation	295:15 343:18
300:23 373:13	261:2 302:22	318:19 325:2	352:2 370:6
407:11 408:15	313:13 359:4	326:7	385:18 399:23
sets 277:4,8	383:2	simulations	400:8 402:6
setting 341:19	sign 416:22	336:4,7	sit 120:6,16
seven 354:9	419:8	simultaneous	279:6 320:10
369:23 370:4,4	signature	224:17 239:2	sitting 198:6
370:13,18	418:13 421:11	single 31:3	285:17
371:9 376:17	significance	93:18 94:2	situation
405:19	188:3	107:6,21	148:22 222:8
several 28:17	significant	148:13 300:20	305:10 311:13
111:24 112:5	24:19 25:9	300:22,24	312:3 326:12
203:3 264:2	233:16 234:9	301:9 306:13	326:13 334:10
359:16 363:9	235:12 236:3	341:5,11,13	335:5 350:9
sheer 254:17	252:8,13 281:1	392:12	361:10 362:8
sheet 419:6,9	351:2,5 352:3	sir 8:6,23 9:16	situations
419:11,14	352:12 365:12	40:10 55:4	108:4 141:16
421:9	365:22 369:21	167:10 170:15	274:4 306:20
short 160:13	370:1 375:5,16	187:9 253:12	336:8 346:18
369:4,9 371:24	384:9,14 385:9	sister 5:2 11:23	349:9 361:7
show 136:10	385:24 388:17	11:24 91:2,6,13	six 112:7
149:8,15 155:6	390:13	91:21 92:5,17	369:20
410:3,7 414:4	signing 419:10	92:19 93:6,14	size 12:2 252:14
showed 140:9	similarly 13:16	112:2 115:14	254:5,12
154:18 155:24	281:15 377:6	117:17,22	260:11 261:4,5
183:14 250:4	simple 44:16	118:7 119:8,12	261:21
391:7,12	simplified	119:18 122:4	skills 136:7
showing 155:8	360:11	127:18 129:13	slide 213:3
189:9 362:8	simplistic	137:9 151:22	249:17,23,24
373:6	301:21	175:12 195:16	slight 379:23
		203:4 207:15	

[slightly - speculating]

Page 72

slightly 242:16 243:1 292:16 341:21 slow 220:20,22 248:1 259:9,10 small 183:21 252:14,18 254:4,16 266:6 278:21 338:20 342:10 360:11 371:10 378:17 378:21 379:20 388:6 smaller 261:4 276:11 snapshot 227:20 society 182:23 183:4 402:4 software 317:12 321:7,9 solicits 173:4 solve 288:21 298:21 313:3 solving 186:5 somebody 29:5 31:9 42:2 63:3 99:2 122:8 130:14 169:13 182:13 194:3 271:17 274:15 288:1 292:11 292:20 293:10 295:4 296:22 298:4 330:21	sorry 12:12 24:24 25:3,6,17 27:22 31:8,9 41:21 44:12 45:17 46:2 53:24 65:7 68:24 74:5,6 76:5,23 78:14 116:8 117:1,1,6 118:4 127:1 133:14 138:15 160:21 165:20 166:21 167:10 167:10 168:11 170:2 171:6 176:12,18 188:24 191:6 193:12 211:12 212:21 223:8 233:19 234:3 235:15 239:10 241:10 250:13 252:2 254:23 264:12 266:20 274:23 279:9 287:5 291:19 293:4 309:21 315:4 318:1 333:23,23 336:14,16 347:20 379:11 380:24 388:13 391:9 400:3 408:10 sort 15:20 23:12 32:15	77:7 87:19 88:11 104:13 104:14 105:15 138:23 164:4 171:9 172:16 184:10 188:5 196:9 209:1 222:9 227:15 238:5 246:3 257:5 264:13 285:20 288:22 301:22 339:3 340:9 365:16 373:23 sought 92:15,18 93:5 404:17 sounds 12:18 369:12 source 372:7,9 sources 144:21 331:12 390:20 south 2:3 space 146:8 194:3 419:6 spalding 2:18 spanning 156:13 speak 45:21 speaking 7:7 80:14 87:2 101:7 139:20 184:24 301:20 speaks 322:21 specialty 46:6 specific 41:18 68:1 84:22 87:5	102:23 103:1 104:12,19 141:16 143:21 143:22 148:5 155:11 161:5 182:6 186:18 210:8 213:18 216:10 217:9 222:2,11,20 236:22 272:2 295:13 296:5 387:3 410:17 specifically 65:19 87:17 88:24 90:11 97:8,11 133:23 142:24 144:22 166:22 221:2 244:24 263:14 283:18 368:4 410:15 411:4 specifics 90:12 128:4 356:8 specified 66:14 286:1 specify 74:18 343:8 specifying 66:15 spectroscopic 146:9 speculate 67:1 70:16 speculating 171:14
---	---	--	--

[speech - stay]

Page 73

speech 199:20 201:9	370:9 378:3 started 8:16	224:22 237:23 259:22 261:9	327:21 328:10 360:13 409:16
spend 58:17 96:20 97:14 162:9	26:10 51:21 52:16,18 58:9 59:10 111:22	261:12 264:13 285:20 287:10 300:17 323:7,9	409:20 statistically 24:19 233:16
spent 50:1,2 53:11,18 54:10 72:19,22 202:17 347:14 405:6	122:13 390:7 403:23 404:7 404:14 starting 53:21 202:2 238:7	324:24 325:12 326:2,18 332:24 370:17 373:5 380:9 387:7 402:13	234:9 235:12 236:3 252:7,13 281:1 339:8 352:12 365:12 365:22 369:21
spoke 20:11,12 21:13 45:23	242:23 333:7,9 333:11	statements 172:16 188:6,9 197:2 371:19	370:1 373:14 384:14 385:9 385:24 388:17 390:12
spoken 71:18	state 1:16 7:17	states 1:1 19:6	statistician 86:11,17
sponsor 12:9	204:21 262:2	40:20 126:24	statisticians 305:14 337:23
sponsored 12:6	270:6 271:13	154:11 186:20	356:19,21
spurious 358:8	271:22 272:1	195:22 211:4	statistics 44:15
square 294:21	304:10 402:18	217:6 262:15	252:17 299:1
ssr 321:9	402:19 410:15	267:4,5,14	302:16 307:24
staff 129:11	411:4 419:5	268:1,8,17	330:14
stage 169:16	stated 11:22	287:18 300:10	status 106:20
stance 153:18	75:9 99:24	368:13 379:19	229:20 250:19
stand 68:6 73:18 302:17 326:18 371:16	134:5 173:21 174:6 177:9 196:21 250:7	416:9 stating 13:19 156:7 160:8	267:7,15,24 309:9,9,24 310:5 311:10
standard 306:14	269:15 416:2 statement 4:11	246:1 statistic 264:11	312:8 314:15 316:6 321:9
standpoint 203:22	13:12 14:15 15:8 19:6,18,20	266:1 statistical 13:1	331:22 333:24 334:5,16,20
stands 163:5 335:18	19:23 20:15 25:7 26:5 27:21	13:14 36:18,24 37:10,16 97:24	342:24 359:14 370:14
start 26:18 49:9 53:15 60:12 141:19 151:8 184:18 218:3 241:15 308:13 331:13 356:10	42:17 49:1 68:6 77:14 156:22 174:6 182:22 185:15 187:7 187:13 206:7 213:13 220:14	100:7 101:13 101:14 131:7 290:24 291:4 292:10 295:3 312:23 323:13	stay 96:5

[steering - study]

Page 74

steering 2:15	strengths 18:6	170:1 175:17	115:14,18,24
stenographer	357:16	178:19 188:22	116:5 117:18
7:1 94:7 124:13	stretch 172:10	202:21 203:9	117:22 118:7
181:15 191:4,7	strictly 139:19	204:18,21	119:8,12,18
207:23 239:4	strike 101:8	211:23 212:11	122:4,13
253:22 398:13	123:15 124:11	318:20 325:3	127:18 129:13
417:5	124:15 149:7	326:7 356:1	129:14,16
stenographic	155:4 164:7	360:7,8,10,18	130:6 131:10
7:10 418:6	197:7 199:8	361:1,2 375:8	135:16 137:10
step 205:22	222:14 224:10	384:17,21	141:19 142:11
275:1 347:9	224:20 410:12	385:5,20	143:2,24
348:5 349:3	strong 55:12	387:18 390:11	144:12,13,20
367:14	73:17,20,21	398:2,7,10,11	145:2 150:18
steps 130:12	74:3,11,16,17	398:16,18	151:22 158:19
275:20 331:15	75:14,15,16	399:21 402:8	160:18 165:1
331:17,19	76:5,6,13 77:21	408:20	169:23 172:7
348:1 351:15	78:1 186:16	study 5:2,3,6,9	173:11,16
365:20,21	struggle 95:22	9:4 11:9,22,23	175:12,17,22
stewart 299:3	408:22	11:24 12:5,6	176:5,24
sticking 185:21	students 80:14	13:6 14:6 16:5	178:21 184:5
stopping 65:9	81:1 86:1 408:6	16:7 17:15,22	186:23 195:16
81:16	studied 139:15	18:6 19:9 21:1	203:4 207:2,9
stops 390:18	studies 41:11	22:15 59:19	207:15 208:12
stories 252:24	56:11,21,23	60:22 63:12	208:21 209:5
377:20 379:2	57:14 88:15	64:4,8 65:15	209:10 210:1
story 339:15	89:10 103:23	73:24 85:15,16	211:6,7,16,21
straightforward	115:13 120:9	85:17 87:22	212:4,11,24
86:8 378:4	122:3 134:3	88:15,17 89:4,4	214:10 215:10
strategies	137:18 140:2	91:2,5,6,7,12	215:22 216:16
306:11	140:23 141:3,6	91:13,21 92:5	216:17,19,22
strawn 38:14	141:12,17	92:17,19 93:6	218:11 219:12
38:22 39:19	142:8 143:4,7,8	93:14,20 100:8	219:13 237:12
street 2:3,8,13	143:9,18,21	111:17,20,21	239:24 240:9
2:19	144:15 146:14	112:2,8,16	241:8,16 244:1
strength 391:11	147:11 154:6,7	113:7,8,12,16	244:18 245:18
	158:7,8,22	113:22 114:15	247:2,4 249:3

[study - sure]

Page 75

252:16 253:2 254:7 259:17 259:20,24 260:1,4,17,18 262:7,23 263:20,21 264:6 269:9,23 272:8 276:19 283:23 285:5 285:12,22 286:20 287:9 287:10,14 288:8 293:15 295:15 303:16 304:17 310:12 313:9 343:18 352:2 355:19 355:20,22 356:3,5,10 357:14,16 358:15,23 360:23 361:12 369:17 370:6 370:24 380:5 380:17 381:13 382:19 385:18 386:23 388:5 388:14 390:15 390:17 391:20 399:23 400:2,5 400:8,20 403:4 403:24 413:10 study's 209:10 studying 104:24 105:12 208:5	stuff 157:10 344:22 stunned 109:23 363:20 subgroup 248:20 252:9 382:21 383:11 411:19,23 412:18 subject 103:8 260:10 261:2 261:20 264:6 384:18 389:14 419:10 submit 16:13 162:4 submitted 169:7 170:10 192:14 suboptimal 301:13 312:2 subscribed 421:12 subsequent 142:18 143:6 218:11 270:17 270:19 278:11 284:4,4 285:13 286:10 288:13 289:5 386:21 subset 352:9 subsidiaries 17:20 substance 206:3 421:8	substantial 243:18 394:7 subtypes 134:4 137:21 suddenly 136:1 154:23 224:3 suffer 179:7 suffering 283:3 suggest 192:11 196:22 suggested 66:21 suggesting 69:16 98:8 305:3 307:2,2 307:17 suitable 271:11 suite 2:3,13 3:4 summarize 24:17 summarized 56:23 summarizes 396:9 summarizing 156:10 summary 160:13 175:4 196:8 super 341:14 341:19 351:8 supervision 418:24 supplemental 214:14 221:18 228:1,14,19	229:14 237:7 239:17 242:3 348:11 351:12 support 6:1 14:11 15:22 28:23 29:21 33:18 34:3 46:15 95:14 96:10,16 98:17 104:9 168:12 168:13 184:15 214:3 262:9 314:19 375:18 supported 168:5,19 supporting 22:20 97:2 supports 28:21 157:19 supposed 42:20 256:4,5 sure 8:5 12:9 12:20 23:14 34:9 41:3 45:3 45:22 55:14 65:24 69:6 81:20 89:16 90:8 93:15 104:17 118:15 128:11 138:22 147:23 155:17 155:17,20 157:3 158:2 159:18 160:22 173:2 175:9 210:23 216:2
--	--	--	---

[sure - talc]

Page 76

225:8 230:4 245:2 248:16 259:3 265:23 283:1,2 286:4 291:8 344:12 355:24 372:5 374:16 380:15 383:1 386:24 389:15 408:21 412:3 surely 105:7 surface 167:20 surge 416:11 surprise 146:17 146:20 surprised 165:11 200:20 surveillance 332:21 survey 142:5 220:17,17 221:23 222:5 225:14 277:22 surveys 276:12 353:15 survival 254:10 317:22 331:22 332:18,21 333:3 342:12 342:14 survivors 411:14,20 susceptibility 253:16 susceptible 253:7 359:13	383:8 suspicious 384:16 switch 367:2,3 370:14 switched 364:17 switching 289:10 sworn 7:4,13 421:12 symptoms 253:9 t t 4:6 318:20 418:1,1 420:2 tab 412:5 table 21:17 47:3,5 64:3 179:8,11 198:11 218:18 218:21 219:4 230:23 235:17 248:24 249:3,4 250:9,18,19 260:23 261:1 265:6 269:9,11 276:1 278:17 279:24,24 282:23 283:4,5 290:21 332:6 342:3,4 347:3 349:2 354:6,6 362:17 363:7 364:21 378:5	379:14 383:20 383:23 392:16 395:12,12 tables 220:11 331:17 take 19:15,17 23:5,6 47:11 78:4,6,23 79:8 81:10,17 83:10 86:11 95:1 136:23 145:19 169:24 171:7 171:10 201:1 202:3,11 203:10 207:24 241:11 258:23 258:24 259:1 269:8 275:20 280:23 282:13 307:18 323:17 323:24 324:1,2 325:5 334:19 361:13 365:9 365:15 366:24 367:3 368:14 369:20,23 371:22 373:1 374:14 379:12 389:21 406:7 407:21 takeaway 186:8 196:18 taken 83:13 133:7 145:22 147:22 154:22 174:18 202:14	259:5 324:9 364:3 374:21 376:9 388:24 400:13 418:6 takes 195:1 307:22 337:21 talc 13:6 14:1 24:20 25:10,14 55:20 57:5,21 89:15,17,20 90:2,13 91:23 92:8,13 106:12 112:1 114:15 115:3 116:15 117:16 118:7 120:11,20 121:12 122:11 142:9,15 143:6 144:5 151:23 152:17 156:11 158:16 173:17 175:20 186:10 186:17 188:14 192:22 194:5 197:4 203:11 203:17 204:14 204:17 205:1 205:13 207:1,4 207:17 208:6,9 208:15 209:7 209:12,15,17 210:2,7 211:9 211:23 212:16 214:19 215:19 219:22 221:6,9 221:14 227:1
--	--	--	--

[talc - ten]

Page 77

237:8 242:16	83:7 94:1 99:14	355:8 356:2	task 57:19,21
242:24 249:9	100:15 101:10	369:16 381:23	58:1 63:20
250:2 256:21	105:7 107:5	408:24	teach 408:5
260:12 261:21	110:23 124:6,9	talking 19:4	teaching 80:24
262:11 264:7	124:10 130:13	41:21 76:23	86:2
265:2 267:4	141:10 143:22	78:13,17,18,20	team 20:7,19
276:9,13,23	147:6 160:16	82:15 93:21	27:1,5,8 45:9
280:23 281:6,7	161:13 179:11	102:23 104:4	50:5
281:8 285:8	182:12 187:8	141:5 143:20	tease 272:21
286:11 291:23	188:3,3,12	149:9 151:8	technical
295:16,17	190:2 196:14	160:22 161:4,7	146:13 325:1
309:23 336:20	201:21 204:9	164:21 166:22	technique
337:9 347:16	209:20 212:9	167:11 184:18	101:20
352:1,8 359:1	231:17 237:2	184:20 191:8	teens 220:5
359:12,18	241:3 262:6	202:17 203:2	224:1,6 225:11
373:7 377:21	268:11 269:5	206:8,9,16	271:3
378:11 379:3	278:2 289:13	223:18 239:6	telecues 356:5
381:14 382:12	289:19 298:1	249:12 252:15	tell 8:22 16:3
385:6 391:23	302:4 309:20	256:11 258:12	28:18 31:1,19
392:21 395:1	309:24 328:19	324:12 336:17	39:3 41:16
396:10 399:11	336:12 339:21	347:1,14,22	60:16 94:23
401:24 403:5	349:21 356:5	349:1 350:8,11	102:13 108:7,8
410:3 411:5,6	360:6,7 361:17	362:3 387:15	159:9 184:4
411:13,22	366:3,9,12,15	391:4,5 394:21	198:13 219:18
412:13,15	381:20 382:6,7	411:11	231:24 252:18
413:1 416:3,11	383:1 391:10	talks 14:13	265:8 282:11
talcum 1:4 56:1	391:20 394:19	104:21 105:3	283:8,10
90:21 203:23	talked 28:17	192:15,17	335:10 344:6
210:12	111:18 116:17	217:11 219:1,5	345:12 407:3
talk 15:4 17:6,8	151:18 160:19	313:13 382:9	telling 46:14
17:13 18:2	160:24 161:2	385:8 412:10	406:24
21:17 22:4,9	161:17 275:10	tamping 331:10	tells 354:4
25:11 28:15	278:12 282:3	tangential	tempting
32:23 33:15	289:18 290:22	321:5	305:20
36:15 39:10	314:14 346:24	tape 8:13	ten 22:23 27:19
41:15 82:16	348:1 352:5		50:1,2,6 259:2

[ten - think]

Page 78

274:19 340:10 399:22 405:15 406:5 tend 49:11 110:4 173:2,6 360:10,19,20 tends 78:7 84:21 tenure 135:2,3 term 14:5 44:15 67:23 101:2 234:12 235:18 369:4,9 371:24 382:12 383:13,14 terms 33:8 76:6 91:5 93:20 100:18 111:9,9 150:21 221:19 255:21,21 257:20 309:3 331:9 361:15 362:18 377:18 terrible 60:11 307:5,21 terribly 309:2 terry 4:15 192:23 193:17 193:20 194:2 195:6 373:19 401:11 test 15:17 361:19 371:16 371:23 tested 348:18 363:8	testified 7:14 testifying 70:11 121:15 testimony 53:5 149:13 testing 367:19 textbook 104:19,21 334:23 335:15 335:20 textbooks 104:18 105:6 thank 83:11 202:5,7 247:17 324:5 371:5 374:17 416:19 theme 87:19 theoretic 240:3 240:11,15 349:22 theoretical 350:3,12 410:21 theory 350:19 thin 231:23 thing 26:12 31:3 49:4 60:11 77:16 79:14 123:23 158:18 172:18 179:22 196:8 208:18 275:2 281:5 282:14 317:23 329:7 337:17 351:22 358:16 366:19 367:9	376:20 391:17 391:18 things 8:12 48:14 71:11 83:24 96:8 101:5 105:3,16 105:17 116:15 141:18 155:22 164:3 169:18 177:22 180:9 199:15 237:3 255:18 269:2,3 286:21 321:10 346:21 347:11 351:16 357:24 366:7 think 14:16 26:16,16 38:18 39:9 40:3 41:13 43:6 46:3,10,11 48:7 49:5 50:13 51:10 52:4 56:4 58:12 59:15 60:1,5 61:2 62:3 63:19 65:4 68:18 71:10 72:13 73:7 74:19 75:7 80:7 80:9,11,20 81:21 82:2 84:7 84:16 87:14 88:9 90:14 93:9 95:5 97:10 99:7 100:24 103:1 104:20 112:11 127:24 132:5	138:9 139:20 139:21 141:15 141:24 145:12 145:16 150:20 151:7 152:12 156:20 162:8 162:13 163:7 163:23 165:3,6 172:9 173:1,7 175:8 176:23 182:5 183:18 184:4,6 185:20 186:2,24 187:13 190:14 190:20 191:9 196:5,6 199:16 200:5 203:16 204:22 207:6 208:10,13,17 208:20 217:22 218:14 220:13 221:1,21,24 224:6 227:21 228:21 229:6 232:23 233:5 234:13,14 237:14,21 238:22 247:19 250:16 251:16 252:19 255:8 255:17 257:24 258:12 259:13 259:22 260:21 260:22 263:4 273:2 277:1,7 283:12 284:8,9
---	---	--	--

[think - tisi]

Page 79

287:7,17,23	195:11 247:14	49:17 50:23	415:9 416:18
288:2,7,18	250:17 276:16	52:8,18 53:11	timeline 53:11
289:4,7,8	379:13	53:14 55:15	144:23
290:15 291:6	thirties 219:3,8	58:8,9,16 59:9	times 27:17,19
296:8 300:13	220:24 221:3	59:10 61:14,20	28:5,18 40:8,12
300:17 303:21	223:2 225:17	71:13 72:19,19	40:14,23 43:16
304:9,11	235:11 236:8	72:22 83:13	44:24 46:23
305:13 306:24	thirty 354:9	90:1,23 97:14	51:15 75:1
307:1 310:9,13	419:15	98:2 102:19	108:5,12 210:8
310:14 313:1	thompson 2:8	118:24 121:13	291:21 301:16
316:8 319:22	thought 25:17	135:21 145:22	411:8
321:11 324:19	27:23 78:13	146:8 148:9	tiny 252:16
324:21,23	123:13 157:3	162:10 175:21	tipping 243:22
325:9 328:6	176:13 193:13	180:10 181:8	tisi 2:3 4:3 7:16
330:12 332:1,2	218:1 249:10	202:6,14,17	8:21 10:8,22
333:1,19 334:2	249:11,12	204:1 213:18	16:1 17:4 18:13
334:3 337:15	286:9 386:16	215:5 216:10	18:16 20:3 21:8
338:14,15	395:23 401:12	217:9 219:15	22:1 24:2 27:6
339:21 342:2	three 58:8,20	222:16 223:5	29:14 30:7 32:8
346:17 347:5	59:8 136:22	224:24 227:14	33:6 35:16
348:24 350:20	137:1 162:7	238:19 244:7	36:14 40:7 42:9
352:19 363:15	217:10 266:13	248:11 250:22	42:22 43:12
368:3,23 372:7	266:16 281:16	252:23 256:22	44:11 45:5
376:4,16,19	282:3,4 296:13	257:1 259:5	47:15,20 48:23
379:14 385:13	313:24 314:4	260:8 261:18	49:13 51:2
390:6 392:21	403:23 404:7	263:18 278:13	52:14 53:17
393:16 398:19	404:15 415:20	281:20 307:16	54:19 57:1,15
400:17,18	throw 103:7	307:18 324:1,9	58:4,19 59:7,17
408:11 409:1	285:12,13	326:16 330:22	61:18 62:5,23
412:4 417:2	288:24 368:15	332:9 333:12	63:23 64:16
thinking 81:12	371:24	347:14 355:17	65:6,23 66:16
86:19 103:16	throwing 283:7	356:6,20 366:4	67:3,21 68:20
104:15 203:15	thrown 298:19	366:8,18	69:8 70:18
286:3 395:21	time 21:1 22:11	374:21 387:4	71:21 72:7,14
third 117:5	28:1,3 41:23	389:21 405:6	74:22 75:11
163:20 175:9	42:12 43:7 44:3	406:15 407:1	76:3,14 77:11

[tisi - track]

Page 80

78:3 79:16	191:19 192:9	370:22 374:23	166:15 181:9
81:19 82:23	194:1 195:3	394:3 395:17	187:13 208:8
83:9,15 88:13	197:6 199:5	397:10,23	237:24 268:13
90:15 91:9,22	200:1 201:3,7	398:21 399:17	348:2 351:15
93:16 94:11	201:15 202:4,9	401:9 402:2	367:17,18
97:16 98:7	202:16 204:7	403:1,19 404:6	408:1
99:12 101:6,22	205:7 207:10	404:16 405:11	tool 148:13
102:4 107:16	208:3 210:15	406:11,17,22	299:2
108:6 109:1,15	215:14 221:16	407:2,6,19	tools 408:4
110:5,22	224:8,19 226:7	408:7 409:18	top 183:23
111:11 112:20	226:19 232:4	410:5,23	213:16 226:24
113:3,20 115:1	232:12 233:9	411:15 414:1	279:5 338:16
116:3 117:13	237:1,16 239:9	414:24 415:4	347:10 392:19
117:23 118:17	240:17 243:20	415:16 416:5	topic 98:19
120:4 121:1,20	246:22 252:4	416:14,20,23	99:3 345:24
122:23 123:5	254:1 255:19	title 163:16,18	total 366:13,14
124:14 125:6	256:9 257:9,14	164:11,16	366:16 405:9
125:21 126:23	257:23 258:20	165:2 302:20	totality 396:4
128:6 129:5	258:24 259:3,7	414:14	totally 34:5
131:3 133:21	267:19 268:22	titled 146:8	41:14 60:14
136:20 139:3	273:13 280:13	413:19	243:10 248:15
140:5,19	284:2 291:9	today 61:21	295:9 369:24
143:12 145:3	292:4 293:6	120:6,16 159:4	touch 81:1
145:18 146:1	295:1 296:20	together 44:19	touched 88:4
150:2 151:17	299:11,21	133:24 177:7	88:10
152:7,15	302:13 303:10	183:7 266:16	touches 114:15
153:14 155:14	304:3 313:7	294:20 321:10	towards 238:10
156:3 158:1	316:3 317:14	394:22 405:7	318:21 327:19
159:2,22	320:1 321:2	told 159:10	328:7,14
160:15 161:23	322:22 323:4	246:7 259:9	330:24 331:23
163:10 164:18	324:11 330:4	385:14	333:18,20
166:3 171:5	344:1 345:10	tomorrow	358:2 373:23
172:3,12 174:3	345:19 346:4	122:9	trabert 5:7
174:15 177:6	350:1,10,22	tonight 417:4	414:16 415:2
180:1 181:3,20	353:4 354:23	took 17:10 37:1	track 135:2
181:23 182:21	358:13 362:5	146:3 153:10	

[tracts - trying]

Page 81

tracts 383:7	53:23 54:7,14	205:9 206:20	390:5 396:12
trade 102:17	57:8 58:10 59:2	209:22 210:9	400:9,21 404:9
103:9 105:18	66:10 68:3,23	211:19 212:1	404:20 405:1
train 123:12	69:12,19 70:5,9	212:20 213:11	405:16 411:24
training 409:24	72:2,9 73:17,24	221:20,23	truly 275:23
410:10	75:18,18 76:8	227:14 229:4	352:10
transcript	76:18 77:2	229:10,17	trust 303:14
418:8,22	78:12 79:20	230:16 232:13	304:5
419:16,17	85:4 90:21	233:18,22	trusted 304:23
transcription	92:17 100:19	235:14 236:17	try 12:16 35:24
421:5	101:15 102:11	237:12,20	106:10 125:4
translate	104:24 105:12	239:17 243:13	160:10 162:15
394:12	105:14 106:14	244:10,22	173:2,4 185:12
transparent	106:22 107:9	248:21 252:10	208:21,24
232:1	107:12 108:16	259:21 260:20	231:21 265:10
treat 307:3,19	109:9 110:14	261:24 262:1	275:21 289:1
treating 307:14	111:1 116:11	263:22 267:5	293:20 316:9
treats 307:10	116:12 117:18	268:2 275:4	352:21 360:3
trend 412:11	118:1,2,24	295:2 306:20	361:4 387:24
trends 47:1,21	119:4,12	308:1 309:10	417:5
trials 346:22	121:22 126:16	310:12 311:7	trying 15:3
trick 93:2	132:3 140:10	312:6,23	24:24 51:18
tried 272:22	141:14 143:3	316:19 322:19	70:21 75:13
275:16 277:5	152:3,22	324:22 333:1	89:5 97:3 99:11
277:16 348:12	154:19 156:17	340:18 341:6	102:18 103:17
360:2 361:11	157:19 158:12	343:2 346:1,15	141:15 157:5
tries 338:2	164:11 170:18	349:22 351:3	164:3 198:6
trouble 308:15	171:24 172:7	352:16 353:9	212:14 228:2
309:4	173:19,20	355:3,17 356:6	240:21 255:8
true 17:23	176:11,24	356:20 357:9	269:21 272:21
18:23 21:3,11	182:4 183:17	357:18,20,21	277:17 288:20
21:13 34:20	186:23 187:21	358:19 359:20	292:15 293:9
35:8,19,21 36:5	192:16 194:6	360:15,17	294:14,20,21
36:9 38:3,7,14	198:3,17	375:19 385:12	296:2 309:13
42:2,14 43:4,16	201:12,12,16	385:14 386:23	327:1,9 328:12
46:17 52:6	203:13,16	388:11 389:3	331:7 332:15

[trying - unique]

Page 82

337:12 346:17 349:18 356:15 356:17 371:6 382:6 tubes 382:21 383:20 388:10 389:1 390:4 tumors 88:6 turn 143:7 260:3 282:20 282:21 twenties 219:2 219:7,22 220:7 220:24 221:3,6 221:14 223:2 224:5 225:19 236:2 274:10 twenty 254:15 twice 34:18 two 11:17 41:5 41:7 54:13 56:16 70:13 131:16 146:4 147:11,20,21 162:7 173:1 200:23 210:7 213:18 216:9 222:16 224:24 228:15 235:10 235:18 254:12 259:12 266:12 269:22 275:2 275:17 276:7 277:3,7 278:24 281:21 282:4 289:24 292:22	327:23 329:12 342:7 343:8 347:5,11 353:15 356:9 type 205:17 327:21 types 379:7 407:16 typical 58:13 85:17 168:22 169:23 typically 43:13 84:22 162:18 318:5 330:17 u u.s. 195:17 ucsf 80:14 127:3 128:9 172:14,21 uh 30:17 214:19 266:8 317:2 378:6 409:3 ultimate 43:1 156:16 204:3 204:15,18,20 ultimately 16:14 205:16 unacceptable 60:14,15 unbiased 209:1 308:4 313:4 327:12 335:9 uncertain 238:16,17	uncertainties 185:18 uncertainty 185:2 262:18 306:15 339:12 340:4 397:18 unclear 107:18 uncomfortable 374:15 under 148:17 168:13 184:10 219:18 230:12 230:24 264:21 264:23 313:14 335:3,7,7 336:7 359:16 418:23 underestimate 306:13 underestimates 306:15 undergoing 169:5 understand 10:12,24 13:21 15:2,11,13 17:22 18:5 35:17 49:4 51:18 52:4 76:4 76:22 84:4 91:4 91:11 98:3,9 106:24 118:9 118:23 119:17 132:20 134:9 135:15 152:2,9 152:16,20 164:19 169:1	170:12 174:7 180:16,18,19 180:21 182:1 199:15 265:20 266:21 270:11 288:21 295:9 296:1,1 298:13 319:14 323:15 327:1,2 344:24 356:16 366:9 367:16 371:8 373:22 389:24 400:19 401:1 understanding 84:20 108:18 108:20 153:4 220:19 326:23 329:3,6 339:23 377:19 understood 16:15,16 22:10 22:11 87:10 100:14 177:15 367:13 unexposed 280:1,4,4,16,16 281:8,9 unfortunate 283:22 309:1,2 unfortunately 148:20 278:20 286:18 unique 175:22 176:5,22,24 178:20 196:2
--	---	---	--

[united - used]

Page 83

united 1:1	usage 227:19	227:11 228:3	364:17 365:10
university	use 8:4 13:6	228:12 229:13	368:15 369:5
34:12	14:1,10 24:20	233:18,21	372:20 373:7
unknown	25:10,14 43:24	234:11,22	375:6,19 377:8
375:10	44:2 56:2 75:15	235:18 242:8	377:21 379:3
unobserved	76:11,24 78:1	242:16,24	380:22 381:1,8
409:10,10,12	80:18 90:13	245:3 249:9	381:14,16,23
unpack 237:15	92:8 100:13	250:2,21	382:8,10,11,12
395:3 396:21	101:2 104:22	256:21 257:21	382:15 383:8
unqualified	105:10 115:3,4	259:18 261:21	385:7 388:7
130:5	117:21 142:15	262:11,24	392:11,21
unrelated 81:9	143:6,19 144:5	263:2 264:4	401:24 403:5
unreliable	147:1 148:19	267:4 270:14	408:4 410:4
22:22 24:22	149:12 154:5,5	271:7,8 272:4	411:5,13,22
25:16 42:14	154:9 156:11	273:23 274:8	412:13 413:1
43:4,14,23 44:6	158:6,6,10,16	274:16,18	413:20 414:21
44:14,19 50:8	173:17 175:19	276:9,13 277:6	used 11:24 13:8
51:21 52:1,5,10	175:22 176:6,8	277:16 278:9,9	15:16 24:4
53:1 55:9,11	176:23 178:21	278:12 280:8	42:11 43:8,14
66:3 75:1 76:16	178:23 186:10	281:13 283:14	43:15,18 44:19
110:21 236:17	188:14 193:8	285:6 287:12	44:21,23 45:3
399:19 400:1	195:11,15	287:14,20	47:16,21 48:3
untrue 396:14	197:4 203:11	289:5,20 290:5	58:3 60:4 74:24
unusable	203:18 204:14	291:23,23	75:8,9 76:7,15
352:16	204:17 205:1	293:15,16,19	77:8 95:6,16
unusual 141:12	205:13 206:3	295:13 296:21	96:10 98:5
142:1 166:17	209:12 210:13	296:21 304:23	104:10 107:8
update 31:4	211:9,18,23,24	309:23 310:16	108:11 112:21
153:11,13	212:3,16,20	313:2 316:8	112:22 146:18
updating	213:6,8,9,20	317:11 321:7,8	147:24 148:15
356:14	215:18 216:12	322:10 332:4	177:11 186:16
upper 86:16	217:12,15	335:11 337:24	197:10 205:18
upward 282:17	219:2,7,8,22	343:6,12 352:1	209:14,16
upwardly	220:23 221:3	352:4,8 354:20	210:2,7 219:24
262:20	221:20 223:1	355:16,18	220:1,3,5,7
	225:3 227:1,3,5	359:1,6,11,18	221:6 223:23

[used - versus]

Page 84

224:1,4,5 225:11,16,18 226:4 227:5 235:9,11 236:2 236:7 244:18 247:9 248:4 258:3 264:7 265:1 274:19 276:23,23 279:9,13 281:7 284:5 285:8 286:11 291:13 293:10 304:15 309:20,21 310:5 312:22 318:4 320:6 321:8,11 325:18 338:11 340:14 341:14 342:1,11,12,23 344:7 348:8 356:4,18 359:15 371:3 381:6 408:3,18 411:8 419:18 useful 259:2 user 189:20 221:9,14 273:5 273:7 279:19 292:12 296:18 338:13 355:2 367:3 394:23 397:3 users 14:5 270:1 279:19 281:18,20,23	282:1 284:21 295:17 296:14 306:7 336:21 336:22 337:11 367:2,4 369:5,5 369:9 372:1 383:14,15 394:8,9,14,15 395:1 396:16 397:5 412:19 uses 146:22 156:7 203:23 276:8 296:22 317:12 321:9 363:9 396:7 using 12:12 13:1 14:19 44:18 100:18 102:9 105:8 106:9,12 123:19 134:13 148:22,24 149:3,11 175:11 192:1 205:19 211:5,6 211:15 217:2 227:6 239:16 241:17 267:21 292:10,18 304:15,18 306:24 307:24 312:11 316:10 318:8,19,20 322:7 333:9,10 337:7,22 338:17 339:7	339:22 343:13 348:7 351:12 360:5 384:22 385:10 392:13 394:20 usually 70:21 103:15 141:17 uterine 92:4 129:19 250:5 314:6 359:9 377:1,8 378:12 379:15 392:13 uterus 388:9 v v 2:3 vacuous 75:3 76:16 vaginal 392:21 vague 179:22 196:19 351:8 validity 305:15 value 174:19 180:9 181:9 187:14 281:13 300:20,21,23 300:24 301:9 340:24 341:6 364:4 365:7 388:20,22 values 282:12 301:15 305:23 318:7 320:7 325:19 326:16 384:3	vandenburgh 37:14 variability 364:23 variable 209:17 339:11 343:15 variables 103:4 104:24 187:18 187:20 311:14 311:20 338:7 338:11,17 339:17 340:14 341:22 342:1 342:11,14,23 409:9,10,11,12 variance 340:15 varies 85:22 variety 195:12 various 14:19 15:16 34:15 77:1 91:24 149:10 194:20 278:13 290:3 368:2 vary 85:21 vast 219:1 versus 91:18 105:16 154:5 158:6 224:5 245:11 254:9 254:13 270:9 279:15 287:19 287:21 298:7 351:5 376:20 397:5
---	--	--	--

[vienna - went]

Page 85

vienna 1:12	203:21 204:15	wants 288:1	317:19 326:9
view 334:19	204:19 205:11	warren 37:9	327:11 330:17
views 58:15	208:24 209:4,7	39:23 40:2 41:4	331:2,7 332:18
69:4	210:20 215:4	washington	333:2,22
violated 305:20	216:2 218:2	2:14	335:14 341:12
violates 171:1	226:14 231:9	waste 215:4	364:22 369:19
vitae 4:10 29:10	231:11 234:20	watch 137:6	390:10 394:22
volume 154:4	241:23 244:14	water 374:10	402:23
voodoo 100:17	248:15 250:10	watkins 38:6	ways 68:22
100:24 101:3	261:13 264:13	39:16	69:2,10,14 95:5
w	265:22 268:12	wave 355:13	263:5,9 301:8
wait 94:7	275:1 285:23	way 26:17,20	343:14 356:9
207:23	286:5,24	44:19 49:11	we've 28:17
walk 77:9	287:15 288:21	51:15 60:9	159:4 190:3
101:11 122:8	289:15,16	74:15 76:20	192:24 197:19
187:1,5,12	298:15 310:15	85:13 89:14	258:4 348:1
265:10 389:22	320:12 322:12	100:5 102:1,16	368:19
wand 355:13	334:22 347:14	107:8 111:3	weak 333:14
want 15:6,7	355:1 356:7	122:19 128:2	weakens 143:1
31:14 42:18	359:22 361:3	128:19 141:23	weaknesses
54:16 65:20	366:20 371:19	141:24 149:1	18:7 357:16
67:1 70:16 74:6	374:4,5,16	150:5,23	website 34:12
76:1 77:9 78:21	376:6 377:16	171:17 177:15	93:14 119:17
82:8 95:1 99:9	379:11 382:23	178:5 183:24	172:6,22
101:1 102:20	384:7,13,24	199:21 209:1	173:14 343:18
103:7 105:19	387:2,24	223:5 225:23	344:4
123:10,11	389:19,21	236:23 253:2	websites 173:8
141:17 148:6	414:4	258:13 266:23	week 150:24
149:2 155:16	wanted 12:19	271:6 274:14	151:20
155:17 157:22	12:19 69:22	274:17 285:10	weeks 200:23
160:8 161:13	71:13 123:22	286:18,23	weinberg 4:21
173:6 179:6	132:9 228:7	289:3 291:13	114:9 130:17
184:12 187:2	244:13 283:20	295:7 301:21	130:23
192:18 201:22	379:13 380:1	304:13 307:18	went 106:21
202:10,20	389:11	308:3 310:10	176:14 363:14
		316:21 317:8	376:19 384:7

[wentzensen - women]

Page 86

wentzensen	23:20 27:4 32:2	138:14 139:19	357:20 362:2
4:19 114:4	32:10,12,22	140:12 143:11	396:19 397:16
115:8 133:9,17	33:1,4 35:11	144:18 145:7	398:5,15
136:4,12 138:4	36:11,24 37:2	151:6 152:12	399:13 400:24
139:5,8 151:2	37:10,16 38:1	153:2 155:10	401:18 402:12
159:12 161:3	38:16,21 39:9	157:21 159:17	403:10 404:3
388:3	39:15,17,24	160:5 162:24	404:11 405:3
whereabouts	40:5,9,19 42:4	164:14 170:20	405:21 407:20
15:7	42:16 43:6 44:8	172:2,9 174:12	408:8 409:19
white 5:4	45:2 47:11	177:3 179:19	410:6 411:1,16
105:15 314:24	48:16 49:8	181:1,17,21	414:6,12 415:3
315:23 317:17	50:22 52:12	191:6,23	416:15 419:1
317:20 322:5	53:6 54:16	194:14 196:5	woman 203:23
322:15 324:13	56:14 57:10	198:20 200:18	211:8,17
332:15 334:4	58:1,12 59:4,15	202:7 204:5	219:12,19
335:1,2 336:5	62:2,13 63:18	205:6 207:6	221:5 228:18
343:2	64:7 65:1,18	208:2 210:11	270:12 272:8
wide 139:23	66:12,24 67:10	221:11 223:1	275:11 276:20
wider 284:11	68:17 70:12	225:7 226:11	290:1,10,13
288:23 397:2	71:8 72:4,11	231:6 233:5	292:23 293:14
width 254:17	74:13 75:7,21	236:20 237:14	338:12
339:13 364:23	76:10 77:5,24	240:14 243:15	woman's
willing 196:20	79:5 83:4,11	246:20 252:1	203:11,16
406:7	88:9 90:7 91:16	255:16 257:4	212:17
winston 38:13	93:9 94:9 97:10	259:1 267:17	women 13:8
38:22 39:19	97:20 98:24	268:19 273:2	106:11 111:19
withdraw	100:21 101:18	280:11 283:17	137:23 138:11
200:9,10 244:6	107:11 108:3	291:2 292:2	175:18 186:16
244:16 288:4	108:18 109:12	293:4 294:7	195:17 207:2
293:12	109:22 110:16	296:16 302:8	207:14 209:6
withdrawn	111:7 112:11	303:3,24 313:1	209:14,16
287:2,3,8	113:1 117:20	317:7 319:22	210:6 215:18
witness 1:12	118:12 119:22	320:23 323:2	222:5 223:6
4:2 6:4 7:4	120:23 121:16	329:15 343:22	227:4 228:3
15:20 16:24	122:16 124:24	345:6,15 350:8	235:9 236:1
18:11 21:5,21	126:18 127:24	350:19 352:18	237:6,9 242:18

[women - yeah]

Page 87

243:3,12,16 244:20 247:9 248:3 269:22 269:23 271:19 272:17,18,21 276:9,11 278:8 279:3,5 285:8 287:12,14 295:15 296:12 296:13 303:14 304:5,23 306:1 306:2 308:17 336:20,22,23 382:20 383:6 383:19 385:11 388:8,9 389:1 390:4 411:7 women's 142:10 143:24 356:3 word 26:16,19 43:14 44:16 74:24 76:13 77:8 78:1,5 79:7 87:11 146:18 176:23 205:22 231:8 245:23,23 258:4 303:5 318:16 333:19 339:7 348:23 352:5 412:7 wording 14:23 177:4 287:16 words 14:10 43:8,18,24 44:1	44:2,8 48:21 55:11,20 76:15 76:17,20,24 77:14 93:19 147:24 155:12 159:8,20 179:3 189:1 292:3 350:2 work 12:17 29:5 30:4,9,10 30:12,13 31:5 35:6,13 37:24 42:19 46:19 47:18,22 79:12 79:12 87:12 95:18 108:20 111:9 135:20 148:2,11 150:8 155:8 156:1 171:8 294:23 346:9,13,15,18 346:20 380:6 380:12 407:17 408:5 409:24 410:10 413:6 worked 29:7 30:19 31:8,10 35:4 36:4,22 37:19,23 38:5 38:13 working 30:23 33:9,12,14,19 36:17 38:17,18 72:21 85:9 118:23 119:1 120:2 254:7	384:5 workings 126:21 167:6 works 162:4 286:18 world 63:13 69:3 106:17 172:6 192:22 209:3 231:3 316:17 worried 328:15 worry 328:13 worth 102:18 worthy 205:2,8 wrap 158:18 190:2 382:6 399:2 wright 3:9 299:19 write 22:13 23:22 40:21 53:2 69:18,23 70:2 71:2,8 172:15 179:4 232:17 writing 23:16 40:20 50:12 51:4,12,16 52:16,18 53:22 86:4,13 99:4 183:24 266:6 302:11 342:10 386:4 403:23 405:3 written 40:15 49:17 50:24	51:8 68:12 70:13 93:17 97:6,11 98:10 98:19 99:3 103:21 104:3 112:1 116:14 117:3 188:17 194:3 302:3 344:11 404:4 wrong 101:14 106:16 139:12 179:15,21 180:23 181:2 186:21 187:4 187:11,23 218:7,13 225:5 225:9 243:16 247:15 279:10 287:4,24 288:10 295:4 310:10 334:2 339:7 345:12 wrote 50:22 53:7,22 70:8 78:19 111:10 117:2 195:5,6 x x 4:1,6 y y 94:10 yeah 7:19 22:16 26:9 32:2 37:2 38:4,4,11 39:16 45:18 46:18 47:14 54:1 61:4
--	---	--	--

[yeah - zoom]

Page 88

69:9 72:17 73:7	212:12 213:6	zoom 12:13 239:6
73:18 79:22	213:19 216:11	
89:23 92:11	217:10 219:19	
100:16 101:5	225:2 270:15	
111:15 116:6	272:3 278:11	
132:11,18	287:19 292:23	
133:14 137:8	293:14 297:15	
139:7 142:5	304:6,24	
143:22 144:9	381:22,22	
149:14 153:2	382:3 414:24	
155:15 156:19	years 36:5	
158:2 165:4,9	56:12 87:20	
191:23 193:3	111:20,23	
194:7,15	112:7,14,22	
203:14 204:19	113:2 118:8,14	
215:2 218:22	131:16 132:16	
226:5 239:21	144:13 210:8	
248:8,23	210:19 211:2	
250:24,24	211:10,11,19	
260:23 264:20	211:24 212:2	
265:10,14,22	213:22 216:10	
273:24 275:5	216:13 219:12	
286:14 287:15	219:13 221:5	
316:20 318:12	225:5 227:4	
322:16 324:19	272:6 292:23	
332:3,10,11	361:13 383:14	
334:10 344:15	399:22 405:15	
362:7 375:22	406:5 410:2,11	
376:21 380:8	yield 301:12	
380:15 390:6	youngest 211:6	
404:14,21	yup 137:8	
412:23 414:3	241:13 374:19	
415:3	z	
year 75:14	zero 366:1	
201:1 210:9	379:24	
211:7,16		

New Jersey Rules Governing Civil Practice

Part IV, Rule 4:14

Depositions Upon Oral Examination

4:14-5. Submission to Witness; Changes; Signing

If the officer at the taking of the deposition is a certified shorthand reporter, the witness shall not sign the deposition. If the officer is not a certified shorthand reporter, then unless reading and signing of the deposition are waived by stipulation of the parties, the officer shall request the deponent to appear at a stated time for the purpose of reading and signing it. At that time or at such later time as the officer and witness agree upon, the deposition shall be submitted to the witness for examination and shall be read to or by the witness, and any changes in form or substance which the witness desires to make shall be entered upon the deposition by the officer with a statement of the reasons given by the witness for making them. The deposition shall then be signed by the witness. If the witness fails to appear at the time stated or if the deposition is not signed by the witness, the officer shall sign it and state on the record the fact of the witness' failure or

refusal to sign, together with the reason, if any, given therefor; and the deposition may then be used as fully as though signed, unless on a motion to suppress under R. 4:16-4(d) the court holds that the reasons given for the refusal to sign require rejection of the deposition in whole or in part.

DISCLAIMER: THE FOREGOING CIVIL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE STATE RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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